The Office of Cancer Centers of the National Cancer Institute

Policies and Guidelines Relating to the Cancer Center Support Grant

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Revised

Includes Page Limits Effective for FY2011 Submissions, NIH Enhancing Peer Review Criteria, Links to 06/09 PHS 398 forms, and NIH Policy Updates

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Policies and Guidelines Relating to the Cancer-Center Support Grant (CCSG)

I Cancer Centers Program: Philosophy & Policies

The NCI-designated Cancer Centers are the centerpiece of the nation's effort to reduce morbidity and mortality from cancer. As a major source of discovery of the nature of cancer, and of development of more effective approaches to prevention, diagnosis, and therapy, they are unparalleled by any other national effort in any disease area. Cancer centers also deliver medical advances to patients and their families, educate health-care professionals and the public, and reach out to under-served populations. An excellent cancer center is a local, regional, and national resource, directly serving its own community and, through the knowledge it creates, the world at large.

NCI designed its cancer centers program to enhance the potential of institutions for scientific discovery and its effective application to patients and people at risk for cancer. The NCI-designated Cancer Centers serve as models of transdisciplinary [1]translational research through development of clinical and public health interventions from fundamental discoveries, and laboratory investigation of clinical and population observations. To decrease cancer incidence and mortality, centers link cancer research initiatives within the center to health service delivery systems outside the center via proactive dissemination programs, education of health-care professionals and the public, and community partnerships. NCI expects that centers, particularly those with the 'Comprehensive' designation, will develop effective research dissemination strategies to eliminate the disproportionate burden of cancer in minority and other underserved populations.

NCI support to cancer centers is intended to foster excellence in research across a broad spectrum of scientific and medical concerns relevant to cancer. To facilitate discovery and its translation into direct benefit to patients and the general public, the NCI awards Cancer Center Support Grants (CCSGs) to institutions that have a critical mass of excellent cancer-relevant scientific research. The CCSG focus on research derives from NCI's conviction that a culture of discovery; scientific excellence; transdisciplinary research; and collaboration engenders a cascade of tangible benefits extending far beyond the generation of new knowledge.
Features of an NCI-designated Cancer Center

Cancer Center *versus* Cancer Research Center: CCSG funding to cancer centers supports research infrastructure; other activities critical to a center's service mission are supported by patient revenues, philanthropy, and state or local government. NCI considered using the term "cancer research center" but chose "cancer center" to emphasize the close association within NCI-funded institutions of research and clinical care, education, and dissemination. Indeed their intimate association distinguishes NCI-designated Cancer Centers from other "cancer centers," which, whatever their credentials in delivery of medical care, generally lack a strong research base to drive discovery and the development of new approaches to disease prevention,

[1] Definition of Transdisciplinary Research: Collaborations in which exchanging information, altering discipline-specific approaches, sharing resources, and integrating different disciplines achieves a common scientific goal. The term 'trans-disciplinary' refers to integrated (not specific to a discipline) research methods, conceptual development, multiple levels of analysis, and science that produces new models and understanding exceeding the sum of the parts.

detection, and treatment. Institutions lacking a research base follow by adopting advances developed elsewhere, but they cannot lead.

A Policy of Inclusion: The purpose of an NCI-designated Cancer Center is to capitalize on all institutional cancer research and research dissemination capabilities. An institution or consortium of institutions with meritorious programs in laboratory, clinical, and population research must integrate these into a single transdisciplinary cancer center research enterprise across departmental, school, and institutional boundaries (e.g., Schools of Medicine, Public Health, Nursing, Dentistry, Allied Health, Veterinary Medicine, Engineering, and Pharmacy; Departments of Psychology, Psychiatry, Sociology, Nutrition, etc.). An institution having both basic and clinical activities, for example, may not submit a CCSG application focusing on basic or clinical research only. A major test of both institutional commitment and the quality of center leadership is to strengthen and integrate all major areas of research present within the institution(s), and to harmonize research with education and care.

Community Dissemination, Education and Information Activities: Cancer centers not only generate new knowledge but also interact within their communities to assure that new knowledge benefits systems, providers and people. Centers are expected to be active participants in state and community comprehensive cancer control planning and implementation. Centers assure that medical advances developed within the center are made available to people outside the center as rapidly as possible via professional and public education, as well as partnerships with public health or clinical service delivery systems. Centers support the translation of intervention programs into public health or clinical practice. The provision of cancer information within their communities; establishment of formal programs for teaching; development of screening, therapeutic and/or preventive interventions; participation of center faculty in science programs for nearby school districts; and collaboration with clinics in underserved areas are a few of the ways that centers extend their reach to patients, populations, and professionals who might otherwise not realize the benefits of scientific and medical advances. The strong interactions of NCI's cancer centers with their communities provide the relationships and organizational infrastructure required for conducting research that improves dissemination, education, and communication, and ultimately enhances the health of populations.

The Six Essential Characteristics of an NCI-designated Cancer Center: Despite great institutional variety, the one common denominator of all successful NCI-designated Cancer Centers is excellence in research. Successful cancer centers have scientifically strong research bases that are funded by peer-reviewed grants from the NIH and other sources, and organized into formal, collaborative, cancer-focused, scientific Programs. In addition to excellence in research, a successful center is organized and administered to maximize the potential of its research base so that the whole is greater than the sum of its parts.

The Six Essential Characteristics of an NCI-designated Cancer Center are as follows:

Facilities: Physical facilities dedicated to the conduct of cancer focused research, and to the center's shared resources, administration, and research dissemination efforts, should be appropriate and adequate to the task.

Organizational Capabilities: The center should be organized to take maximum advantage of institutional capabilities in cancer research, and to appropriately plan and evaluate center strategies and activities.

Transdisciplinary Collaboration and Coordination: Substantial coordination, interaction, and collaboration among center members from a variety of disciplines should enhance and add value to the productivity and quality of research in the center.

Cancer Focus: A defined scientific focus on cancer research should be clear from the center members' grants and contracts, and from the structure and objectives of its formal Programs.

Institutional Commitment: The center should be recognized as a formal organizational component with sufficient space, positions, and discretionary resources to insure its stability and fulfill the center's objectives.

Center Director: The director should be a highly qualified scientist and administrator with leadership experience and institutional authority appropriate to manage the center and further its scientific mission and objectives.

NCI Designations

Cancer centers have developed in many different organizational settings, reflecting considerable diversity in the size and complexity of their research emphases. Whether organized as a freestanding center, a center matrixed within an academic institution, or a formal **research based** consortium under centralized leadership, all centers are judged by the same scientific, organizational, and administrative criteria. NCI recognizes two general categories of centers:

A **cancer center** has a scientific agenda that is primarily focused on laboratory, clinical research, or population science or some combination of these components. Such centers are encouraged to stimulate transdisciplinary research. All areas of research should be linked collaboratively. Cancer centers with clinical components are *expected* to initiate and conduct investigator-initiated, early phase, innovative clinical trials and to provide leadership for, and participate in, the NCI cooperative groups.

A **comprehensive cancer center** demonstrates reasonable depth and breadth of research activities in *each* of three major areas: laboratory, clinical, and population-based research, with substantial transdisciplinary research that bridges these scientific areas. A comprehensive cancer center is expected to initiate and conduct investigator-initiated, early phase, innovative clinical trials and to provide leadership for, and participate in the NCI cooperative groups. An NCI-designated Comprehensive Cancer Center must also demonstrate community service, outreach, and dissemination; and education and training of biomedical researchers and health care professionals**.**

Consortium Centers

Cancer centers have become more complex as mergers and strategic alliances blur long-familiar institutional identities. NCI supports consortium centers, in which investigators from separate but partnering scientific institutions contribute actively to the development and actualization of the cancer research agenda; these formalized relationships have the potential not only to strengthen the science of the center as whole, but also to extend the benefits of cancer research beyond existing borders. Consortium centers demonstrate a high level of scientific engagement and interaction, with each member institution adding strategic value to the research mission. At the time of submission consortium applications must demonstrate integrated research (as evidenced by a history of collaboration, including authorship of grants and publications) and mechanisms for including

geographically dispersed members in programmatic activities and ensuring access to shared resources. Partnerships between research institutions serving special populations or located in geographic areas not currently served by an NCI-designated Cancer Center are particularly encouraged. Common fundraising and a joint Internal Review Board for evaluation of all cancer research across the partner institutions are encouraged, but not required. Formal written agreements should be in place to ensure the stability and integration of the consortium partnership, including:

- Resolution of differences at the highest levels of institutional leadership.
- A single Protocol Review and Monitoring System and Data and Safety Monitoring Institutional Plan governing cancer clinical trial protocols across all partner institutions.
- An integrated recruitment process to meet the strategic goals of the center.
- Uniform availability of the benefits of clinical research across all consortium institutions.
- Full eligibility for leadership positions, participation in formal scientific Programs (see Part II, Section 8), and access to shared resources for all members.
- Authority of the center director

-To integrate cancer relevant scientists into the formal scientific programs of the center.

-For all CCSG-supported shared resources, including those located in partner institutions.

A comprehensive designation may be based on research in the primary institution alone, or on supplemental strengths of the research in both primary and partner institutions. Grants of the partner institutions may be counted toward Program eligibility and calculation of the CCSG/NCI funding ratio, pending a successful peer review. Specific information must be provided in the appropriate sections of the application and additional review criteria will be applied in the evaluation of consortium centers (see Parts II and III).

While the terms applied to research partnerships may vary (e.g., some centers may refer to the above arrangement as a research affiliation, rather than a consortium), they should be clearly distinguished from other types of arrangements, such as clinical networks or affiliations with community hospitals designed primarily for the purpose of enhancing clinical trial accrual or expanding the center's patient base.

Major Research Areas and Interactions

Transdisciplinary and Translational Interactions between Laboratory, Clinical and Prevention, Control, and Population Research: A cancer center should feature vigorous interactions across its research areas, and facilitate collaboration between laboratory, behavioral, epidemiologic, and clinical scientists, and the scientific Programs of which they are a part. These collaborations should facilitate rapid transfer of clinical observations to laboratory experiments, and promising discoveries in the laboratory to innovative behavioral and medical applications in prevention, detection, diagnosis, treatment, and survivorship. In geographic areas with multiple cancer centers, collaborations among centers may be appropriate. Centers having only laboratory research components are encouraged to seek collaborations with clinical units elsewhere, with industry, and with the NCI to facilitate the translation of fundamental discoveries into tangible patient benefit. Although no particular

organizational configuration is mandated by these guidelines, the center's organizational approach should serve the science and be appropriate for the institution, with reasonable breadth and depth of cancer-focused, scientific faculty and dedicated facilities for support of the center's research areas:

Laboratory Research: Centers should use their base of support to promote basic discovery and transdisciplinary interactions between scientists engaged in laboratory research and, where possible, to stimulate collaborations among investigators in basic laboratory and other research areas.

Clinical Research: A cancer center should be a major source of innovative clinical studies that can be exported, for example, to NCI's cooperative groups or directly into general medical practice. Clinical studies should involve relevant laboratory research whenever possible. In addition to fostering translation between the laboratory and clinic and conducting early proof-of-principle clinical trials, cancer centers should take leadership, as well as participate, in NCI's clinical cooperative group trials.

Prevention, Control, and Population Research: Cancer control research is the conduct of basic laboratory and applied research in the behavioral, social, and population sciences that, either independently or in combination with biomedical approaches, reduces cancer risk, incidence, morbidity, and mortality. The scope of this research is extensive, including pre-intervention behavioral and bio-behavioral research, randomized clinical trials involving healthy and at-risk populations or survivors, and research focusing on dissemination and diffusion of effective medical and behavioral therapies. Prevention research is directed at healthy or asymptomatic populations, including those at high risk and/or those with detectable precancerous lesions, and cancer survivors. Not every cancer center will conduct research in all aspects of prevention, control, and population sciences. However, centers should demonstrate grant support not only in epidemiology, but also in several other areas of primary prevention, early detection, health services, dissemination, palliation and survivorship research.

Relation of the CCSG to the Cancer Center as a Whole: The many functions of a cancer center in the areas of research, patient care, education, dissemination and outreach rely on a diverse base of support including federal, state, and local government; private industry and foundations; third-party payers; and private philanthropy. Within this very broad range of activities, the CCSG has a comparatively narrow focus. The CCSG is intended to provide support for activities related to the peer-reviewed research base of the cancer center. Although the CCSG usually comprises a relatively small proportion of a center's operating budget, it supports an important part of the research infrastructure, stimulates innovation, and encourages transdisciplinary and collaborative research. An effective clinical or comprehensive cancer center fosters good patient care through the close association of care and research. The effective communication of research findings between basic, clinical, and population science venues distinguishes the research-oriented cancer center from organizations dedicated only to care and service. Research in cancer centers contributes directly to the continuous advancement of services provided by the center and its close regional affiliates and offers patients options for prevention, diagnosis and treatment that may not be available elsewhere.

The Relationship of Centers to Each Other: Cancer centers, crucial nodes in the NCI's multicenter trials programs in treatment and prevention, relate to each other in complex ways. Cooperation among centers is critical for the success of NCI initiatives. Centers collaborate with each other to realize common goals outside the sponsorship of NCI, as shown by the formation of voluntary consortia of centers and by joint participation in collaborative studies sponsored by private industry.

As a support mechanism for a center's research base, the CCSG is focused on the individual cancer center; however, collaborations with scientists in other NCI-designated Cancer Centers may be helpful for maximizing research productivity, broadening applicability of study findings, enhancing translation, and improving dissemination capabilities.

Collaborations with NCI-funded Programs and Investigators: Cancer centers are encouraged to collaborate and coordinate their clinical research efforts with other NCI-funded programs and investigators (e.g., Cooperative Groups, Specialized Programs of Research Excellence (SPOREs), early clinical trials networks, other NCI-supported multi-site clinical trials networks and R01 and P01 investigators. These collaborations may include advancing research ideas from pilot studies to phase 3 trials (with transfer between various NCI-funded programs where appropriate), providing correlative science services for large multi-site studies, and participating in multi-site trials conducted through the NCI-supported clinical trials system.

Interactions with Industry: Cancer centers may serve as important transdisciplinary research platforms for evaluating the most promising industry products for early detection, prevention, diagnosis and treatment of cancer. Centers are therefore encouraged to engage with industry in scientifically promising studies of new risk assessment (e.g., screening, diagnostic, prognostic) tests or equipment, preventive or therapeutic agents through clinical trials designed by center investigators, and field-testing of new technologies important in the discovery process. Such studies can benefit from CCSG resources if the center plays a key role in both the intellectual and operational aspects of the study (e.g., an investigator initiated trial with the agent supplied by industry, etc.), findings are made available to the biomedical research community, and the study is consistent with current federal regulations regarding use of grant funds in projects involving industrial partners.

Budget and Funding Policies

Time Limitations: CCSG awards will generally be for periods of up to **5** years.

Some Restrictions on Allowable Budgets: Requested and/or awarded funds may not duplicate or replace costs normally included in the institution's indirect cost base or various services and benefits normally provided by the institution (e.g., purchasing services, personnel services, and other ancillary services) in support of other research organizations (other centers, departments, institutes, etc.). In general, CCSG funds should not be used to compensate for NIH/NCI administrative reductions of active research grants, cooperative agreements, and contracts. CCSG funds may not be used to pay for shortfalls in funded research projects due to over-expenditures on the funded project or NIH reductions in awards. The CCSG funds are not intended to supplement or offset any patient costs, even those directly related to clinical research protocols, including costs for parking, taxi fares, meals, or hotel rooms. The cost of clinical trials should be supported by their respective funded research projects. The CCSG, however, may support research pilot studies as allowed by the developmental funds and protocol specific research component (See Part II). Signatures by the principal investigator and the business official on the face page of the CCSG application officially attest that all of the requested costs comply with these conditions.

Renewal (Type 2) Applications - Size of Total Request: Applicants should contact the Office of Cancer Centers to determine the current status of any formal budget caps and their particular provisions. *In the absence of a formal budget cap, the following policy applies:*

Centers have the flexibility to develop budget requests in relation to the size of their cancer-relevant research base. The CCSG is only one of many sources of funding available to centers for support of their research programs.

A ratio of **0.15** between the size of the CCSG award and the size of the NCI portion of a center's research base (calculated for the last completed fiscal year) serves as an easily verifiable benchmark of the size of a CCSG award. As funding from other NIH institutes is not verifiable as cancer-relevant, it is not used in the benchmark calculation. Centers with budget requests significantly exceeding a ratio of **0.15** should provide compelling data that the cancer focus and scientific excellence of their formal research Programs, and the close and sustained integration of investigators from consortium institutions, clearly justify a larger award.

New (Type 1) Applications - Budget requests from a center with no current CCSG grant should not exceed $1,000,000 direct costs for year one (the budget in subsequent years may receive cost-of living adjustments, depending on the NCI policy in effect for the fiscal year). The NCI will consider exceptions to the general limitation on budget requests for Type 1 applications from centers with a recent prior CCSG award that has been phased out because of an unfundable impact/priority score.

Peer reviewers will be asked to carefully assess budget requests exceeding the 0.15 ratio discussed above; furthermore an award also can be reduced administratively at the discretion of the NCI. The cap on the budget request for a first-time application is largely predicated on the limited organizational track record of a newly applying center.

Resubmissions. Applicants may submit a resubmission application, but such application must include an Introduction addressing the previous peer review critique (Summary Statement). See new NIH policy on resubmission (amended) applications (NOT-OD-09-003, NOT-OD-09-016).

Competitive Revision Applications support a significant expansion of the scope of the P30 Cancer Center Support Grant. The parent award must be active upon the competitive resubmission application and no-cost extensions, where applicable, must be in place. The PI must be the same as that for the parent award. Competitive revision applications are accepted only in response to targeted NIH funding opportunity announcements and must undergo peer review.

Administrative Revision Applications: Depending upon the availability of funds, the NCI will consider administrative revisions to CCSGs to pursue important, short-term scientific opportunities needing immediate attention that could not be initiated and sustained through the normal, competitive grant process (e.g., R01s). Interested centers should contact the program director of their grant to inquire about availability of such funds.

Sources of Budget Flexibility in a CCSG: The CCSG assists institutions by providing support for research infrastructure, such as program leaders, center administration, shared resources and services, and developmental funds for new initiatives. Funds for these purposes stabilize the organization and functioning of a center, provide centralized access to shared resources that are not attainable through other granting mechanisms, and enhance the center's flexibility to pursue new scientific opportunities as they arise.

CCSGs are administered under the provisions of NIH Terms of Award (http://odoerdb2.od.nih.gov/gmac/nihgps_2010/nihgps_ch8.htm). Requests for carryover of unobligated funds in excess of this amount will be reviewed by NCI to ensure funds are necessary for completion of the project;

additional information, including a revised budget, may be requested from the grantee as part of this review. If it is determined that some or all of the unobligated funds are not necessary to complete the project, the NCI may take one of several actions: 1) use the balance to reduce or offset NIH funding for a subsequent budget period, 2) restrict the grantee's authority to carry over future unobligated balances, or 3) a combination of items 1 and 2, above. **The Federal Financial Report must specify the amount to be carried over. Any amount not specified for carryover may be used as an offset for a subsequent budget period.**

Additionally, center directors have considerable flexibility to move funds between budget areas in response to changing needs and opportunities. The center director may increase any budget category rated at least excellent by peer reviewers by up to 25 per cent over the level approved by peer review without prior NCI approval. Rebudgeting of funds into areas rated less than excellent by peer review requires prior NCI approval, which will normally be granted if a proposed investment would significantly improve the quality of an area important to the center. Competing continuation applications should therefore account for significant rebudgeting decisions with appropriate explanations and outcome information.

Funding Policies: Peer review of new, renewal, resubmission, and targeted competitive revision applications over the course of a fiscal year results in a range of impact/priority scores for approved applications. Each year, NCI establishes a funding policy for the Cancer Centers Program to separate applications deserving continued funding from those that do not. Applications with meritorious scores are funded in accordance with the NCI funding policy in effect for the fiscal year. Applications that are not selected for funding will receive either no funding (new, resubmission, or targeted revision applications) or phase-out funding at negotiated levels (renewal applications). During the period of phase-out, the center should be able to revise and resubmit an application that addresses the concerns of peer review. The time limit on resubmission applications is 37 months; after that time, the application must be submitted as new.

While no cap limits the size of renewal increases in individual awards, the peer review process and the NCI fiscal year funding plan will determine the overall budget for the NCI Cancer Centers Program. Peer review plays a major role in judging the merit of the application and justification of budget requests. Clearly however, many factors affect funding levels for individual cancer centers, such as the overall availability of funds, the need to assure entry of meritorious new centers into the program, a significant research focus on underserved populations, and other considerations.

The ability of NCI to pay awarded CCSGs at recommended levels varies from year to year with the size of the congressional appropriation. In years of significant budgetary constraint, funding plans may spread the impact over the entire program (non-competing as well as competing grants) to reduce the adverse impact on competing centers. If funds become available in future years, restorations may be considered.

While many cancer centers have been funded over a long period of time, the program does undergo turnover. A center that has lost its CCSG may reapply and recompete successfully for CCSG funding once its deficiencies have been corrected.

II. Submission of New, Renewal, Resubmission Applications for a Cancer Center Support Grant

These guidelines outline the National Cancer Institute's procedures for submission, acceptance, and review of an application for a Cancer Center Support Grant (CCSG). CCSGs are provided through the P30 grant mechanism to qualified applicant institutions that wish to become NCI-designated Cancer Centers and have successfully met a series of competitive standards associated with scientific and organizational merit.

The essential purpose of a CCSG is to foster excellent science and productive interactions within institutions that already have a substantial research base. The application for a CCSG should focus on the overall excellence of the research base, the extent of the value added to the cancer center by CCSG support, and the effectiveness of the leadership of the cancer center. Supporting materials should be presented in sufficient detail to convince peer reviewers that all requests for resources are justified.

Before an application is submitted, staff members of the Office of Cancer Centers may assist applicants by providing advice on a range of matters relating to the NCI Cancer Centers Program as a whole, funding policies, and strategies for assembling a cogent and persuasive application. For more information, call or write to:

Director, Office of Cancer Centers
National Cancer Institute
National Institutes of Health
6116 Executive Blvd, Suite 700, MSC 8345
Bethesda, Maryland 20892-8345 (for Express mail, use Rockville, MD 20852)
Tel: 301.496.8531
Fax: 301.402.0181

Eligibility Requirements

Only Research Institutions in the U.S. are Eligible to Apply.

Only One CCSG Application per Institution: The CCSG aims to take maximum advantage of the spectrum of resources available within a cancer-research community. Because the major purpose of a cancer center is to catalyze interactions among research groups from diverse departments and disciplines, different components of an institution should not submit separate CCSG applications. NCI encourages applications from consortium centers, particularly those addressing the needs of special populations or in geographic areas not currently served by an NCI-designated Cancer Center. All consortium applications must demonstrate integrated research (as evidenced by authorship of grants and publications) between the partner institutions, and mechanisms for including geographically dispersed members in programmatic activities and ensuring appropriate access to shared resources (See Consortium Centers, Part I).

Funding Base: An applicant institution must have a base of at least $4,000,000 in annual direct costs of peer-reviewed, cancer-related funding. If the cancer center is formed as a consortium of institutions (i.e., if several

different institutions are functioning as *full participants* in the center), the funding base of the center will be the sum of the funding bases of the individual institutions making up the center.

Sources of Support That May Be Included for Determining Eligibility to Apply for a CCSG are:

NCI Support including the following prefixes for peer-reviewed grants, cooperative agreements, and contracts: R01, R03, R18, R21, R24, R25E, R25T, R29, R33, R35, R37, R41, R42, R43, R44, R55, P01, P20, P30s other than the CCSG, P50, U01, U10, U19, U54, U56, T32, K and F series awards and N01s (excluding SEER and other N01s funding materials or services).

Support by Other NIH Institutes and Funding Organizations. Submit non-NCI support information to determine the eligibility of applicants for a CCSG *only* if the applicant's NCI support is below the minimum. Grants and research contracts from other NIH institutes, and grants from the National Science Foundation (NSF), the American Cancer Society (ACS), and a number of other funding organizations can be included in the minimum if they comply with the NCI Referral Guidelines; an updated list of approved organizations is available at http://cancercenters.cancer.gov/documents/fundorg.pdf

Awards from other funding organizations that utilize a peer review and funding system equivalent to that of the NIH may also apply toward the minimum; these funding sources must be approved by the NCI prior to application.

Sources of Support That May Not Be Included: R13 grants, awards from commercial organizations, and NCI or NIH contracts that fund primarily the production of materials and/or services in support of research (e.g., SEER [N01], CIS [N02], and similar contracts and construction grants).

If the minimum funding base cannot be confirmed by a simple examination of the NCI's grants database, the applicant should provide the following additional information: (1) copies of existing documentation (e.g. award statements) of NCI-supported research projects relevant to eligibility showing the PI, grant or contract number, title, direct-cost funded level for current year and total award period;

(2) copies of existing documentation of all non-NCI-supported research projects to be used to reach the $4,000,000 minimum, showing PI, funding agency, identification number of funding agency, title, direct-cost funded level for current year, and total award period. Also, copies of existing descriptions of each non-NCI-supported research project should be provided.

Key Dates in the Grant Application, Review and Funding Process

Pre-application Consultation	Sept-Nov	Jan-Mar	May-Jul
Application Receipt Date	January 25	May 25	September 25
Site Visit	May/Jun	Sept/Oct	Jan/Feb
Review Committee Meeting	Jul/Aug	Nov/Dec	Mar/Apr
NCAB Meeting	Sept/Oct	Jan/Feb	May/June
Earliest Start Date	Dec. 1	Apr. 1	July 1

Notify NCI staff well in advance if meeting receipt dates will pose a difficulty.

Pre-application Consultation (Highly Recommended)

A pre-application consultation, while not required, is highly recommended. Pre-application consultations may be conducted via in-person meetings between NCI staff and center leadership at the Office of Cancer Centers offices or videoconference. The consultation, intended to help the applicant understand the CCSG guidelines, and discuss strategies for preparing a competitive application, should be scheduled well in advance of the due date for submission. NCI staff will clarify the intent of the guidelines, discuss funding trends, share generic information about reviews of CCSG applications from similar institutional settings, and describe the peer-review process. The applicant can define which issues would be most helpful to discuss and then work with NCI program staff to decide what information is most appropriate to provide. The following are specific examples of items that help NCI staff understand the plans of first-time applicants:

Background and responsibilities of the cancer center director and the key senior leaders of the center.

Diagram showing the reporting, programmatic and advisory structure of the center; its relationship to the organizational structure of the institution as a whole; and a list of external advisory board members.

How the center expects to meet the six essential organizational and administrative characteristics of an NCI-supported cancer research center.

Formal scientific Programs and their projected leadership, and criteria for selecting Program members.

Direct-cost budget estimates (in aggregate, not itemized) for the first year for each allowable budget category and individual shared resource.

List of active peer-reviewed research grants, cooperative agreements and contracts, grouped by the formal scientific Programs that will form the total research base of the cancer center. Typically, this listing is longer than the research base used to meet eligibility requirements. For each project, list the principal investigator, project title, direct-cost dollars for the current year, and the total project period (e.g., 5/01/02 - 4/30/07).

Formatting Instructions for New and Competing Continuation CCSG Applications

These formatting instructions supplement those of the PHS Form 398 (rev.06/09). Adherence to these instructions will greatly assist peer reviewers in identifying sections of the application and in matching them with the corresponding review criteria listed below.

All pertinent information needed for evaluation should be included in the body of the application as concisely as possible. Inclusion of material not essential to making a center's best case for funding dilutes the message and distracts reviewers from the major points of the application.

Page Limitations apply only to the narrative parts of each section including descriptions, objectives, goals, rationale, accomplishments, tables, figures, charts, etc. They do not include budget pages; budget justifications; biographical sketches; publication lists; tables on shared resource usage, clinical trial accrual, or Protocol Review and Monitoring System activities; or lists of grants. Page limits are maxima and are not meant to suggest the minimum or optimum length of sections.

Letter of Agreement to Accept the Application: At least 30 days prior to the receipt date, contact NCI program staff to obtain prior agreement to accept the application for review. All new and competing continuation applications involving budget requests of $1,000,000 or more in direct costs, must have written approval.

The Office of Cancer Centers will notify the potential applicant by letter or e-mail that the applicant is eligible to submit a CCSG application and that NCI is willing to accept it for review.

If, for any reason, the application is not submitted by the expected date, obtain a new acceptance letter for the new planned submission date.

The letter of agreement to accept the application should be included as the cover page of your submission.

1.0 Face Page: The "principal investigator" is the cancer center director or designee; the "applicant institution" is the fiscally responsible institution of which the cancer center is a part.

2.0 Description, Performance Sites, and Key Personnel: Provide a description, limited to the space provided on page 2 of the PHS Form 398 (rev.06/09); of the CCSG-related organization and formal research Programs of the cancer center, and of the request for support through the CCSG. Provide a list of performance sites (including hospitals) and key personnel as per PHS Form 398 (rev. 06/09) instructions.

3.0 Include a **Table of Contents** for all major sections and subsections of the application.

4.0 Prepare a **Consolidated and Summary Budget Request** per PHS Form 398 (rev.06/09).

5.0 Standard Cancer Center Information (No page limit)

These Summaries (see Attachment for instructions and formats) itemize for easy reference the center's formal research Programs, shared resources, base of funded research projects, patient information, clinical research

protocols, and a comparison of current and requested budgets.

Summaries 1a, b, c, and d describe the Center's senior leadership (e.g., cancer center director, deputy director, associate directors, etc.), leadership of the proposed Programs and shared resources, and cancer center membership.

Summary 2a lists all active cancer-relevant projects competitively funded by sources external to the fiscally responsible institution of which the cancer center is a part, as of the date of preparation of the summary. Grants are listed alphabetically by principal investigator in two parts--active funded research projects, and training and career development grants.

Summary 2b summarizes the funding by category. Together with Summary 2a, it describes the size and scope of the Center's funded research base.

Summary 3 provides cancer registry data regarding the numbers of patients newly diagnosed and treated at the cancer center and the number placed on therapeutic studies by cancer site. (Data in Summaries 3 and 4 may not correlate and should not be cross-referenced.)

Summary 4 lists clinical research protocols open at the center during a recent 12 month period, sorted by Program, category of research, sponsor, and principal investigator. (Data in Summaries 3 and 4 may not correlate and should not be cross-referenced.)

Summary 5 compares the current and requested CCSG budgets in each CCSG budget category.

6.0 History and Description of the Cancer Center Specifically Describing the Six Essential Characteristics of the Cancer Center: Limit 30 pages

6.1 Director's Overview

Provide a short history and overview of the cancer center, especially its research activities. Briefly describe the most important research accomplishments of the center during the last period of support and the general plans for the future scientific development of the center. If a consortium center is being presented, clearly outline the contributions of each institution, and the history, objectives, and benefits of the consortium arrangement. Describe the formal written agreements in place to ensure maximum integration and stability across all institutions involved in the partnership. Discuss progress in integrating research to date and facilitating access for members to programmatic meetings and retreats and to shared resources.

6.2 Six Essential Organizational and Administrative Characteristics of Cancer Centers

Describe specifically the structure of the cancer center with respect to:

Facilities: Physical facilities dedicated to the conduct of cancer focused research, and to the center's shared resources, administration, and research dissemination efforts should be appropriate and adequate to the task. Centers are clearly more successful in establishing a distinct identity if they have an identifiable physical location. All members of the cancer center need not be located physically in facilities controlled exclusively by the center; however, location of members across Program areas (basic, clinical, cancer control, and population science) in close physical proximity enhances shared use of resources and facilitates scientific interaction. Even

if proximity is impossible, center shared resources should still be reasonably accessible. Adequate administrative oversight of facilities providing shared resources is essential.

In your application, discuss the appropriateness and adequacy of the facilities in relation to center identity and functions. Provide a simple map that illustrates the geography of the center, the location of its major activities, and the physical relationship of any consortium institutions to the main campus. Indicate how access to shared resources and communication are facilitated.

Organizational Capabilities: The center should be organized to take maximum advantage of institutional capabilities in cancer research, to appropriately evaluate and plan center strategies and activities, and to promote joint initiatives, collaborations and interactions within and among its Programs. This is a particular challenge in a large and diverse university or when multiple institutions are included. A center should have**:**

- An overall programmatic structure that effectively promotes scientific interactions and takes maximum advantage of the institution's cancer research capability (this is particularly important to explain when the center includes multiple participating institutions in a consortium arrangement).

- An efficient and cost-effective administrative organization with clear lines of authority.

- The use of a standing external advisory body (appropriately balanced for laboratory, clinical, cancer control/population science, and administrative expertise) that meets at least once yearly, and provides objective evaluation and advice in a report to the center director.

- Internal advisory, decision-making, and priority setting processes for the conduct of center activities.

- Appropriate processes for determining and sustaining individual membership in the center based on productivity, research direction, and participation in cancer center activities.

Your application should discuss the organizational structure and capabilities of the center. Describe how the organizational arrangements take maximum advantage of institutional capabilities in cancer research and promote joint initiatives, collaborations, and interactions within and among its programmatic elements.

Describe the external advisory bodies that provide independent input to the center director, as well as the internal governance processes for decision-making and priority-setting, and the criteria and processes for determining and sustaining the membership of individual investigators in the center.

List the non-aligned members in alphabetical order and in a few sentences describe their departmental affiliations, areas of expertise and research interests. If a significant proportion of the membership (i.e., greater than 10%) is not aligned with any of the center's scientific Programs, describe the strategies used to take advantage of their scientific expertise in furthering the research objectives of the center.

Present the center's strategic planning and evaluation processes. *No separate, formal written strategic plan is required*.

In addition, consortium centers should include a discussion of the following:

- How differences are resolved among consortium institutions.

- How benefits of clinical research are made uniformly available across all consortium institutions.
- How consortium institutions integrate recruitment processes to meet strategic goals of the center.
- Authorities of the center director over CCSG-supported shared resources and integration of scientists in consortium institutions.
- Access of all members to leadership opportunities within the center.

A copy of formal written agreements documenting specifics of the consortium arrangements and commitments should be included with the application.

Transdisciplinary Collaboration and Coordination: Substantial coordination, interaction, and collaboration among center members from a variety of disciplines should enhance and add value to the productivity and quality of research in the center. These activities maximize the potential of the institution, whether small or large, to conduct transdisciplinary and translational research. An actively functioning center promotes innovative and interactive research opportunities through the formation of formal scientific research Programs, comprised of groups of investigators who share common scientific interests and goals and participate in competitively funded research and in publications. Both inter- and intra-programmatic collaboration is important.

In this section, summarize the center's major scientific strengths, its principal research opportunities, and the transdisciplinary coordination and collaboration between cancer center members, including intra-and inter-programmatic collaborations and those involving consortium institutions. Discuss how productivity and quality of translational research in the center is enhanced by these collaborations. Describe ways in which the center promotes creative, innovative, high-quality, and interactive research opportunities.

Cancer Focus: A defined scientific focus on cancer research should be clear from the center members' grants and contracts, by the structure and objectives of its formal Programs, and the collaborations between laboratory researchers and others who are more directly concerned with application of research knowledge. While the definition of cancer research is not infinite, NCI recognizes that many aspects of cancer research are resistant to neat labels and that cancer-relatedness should be a matter of flexible interpretation.

In this section, discuss how the center's grants and contracts, its programmatic structure and objectives, and the collaborations between laboratory, clinical and public health scientists reflect a clearly defined scientific cancer focus. Describe the most important discoveries occurring in the center during the last period of support to help reviewers understand what the center's investigators consider their most important achievements.

Institutional Commitment: The center should be recognized as a formal organizational component with sufficient space, positions, and discretionary resources to insure organizational stability and fulfill the center's objectives. The CCSG makes a major financial contribution to an institution's research infra-structure. The NCI designation lends stature to an institution by attracting patients, industry research support, and philanthropy. The NCI substantially invests in cancer centers and expects similar commitment of the institution(s) to the center. Commitments of parent institutions to the cancer center frequently include the following:

- Recognition of the cancer center as a formal organizational component with a distinct identity.

- Provision of research, clinical, and administrative space and positions.
- Provision of central discretionary funds (e.g., philanthropic funds, indirect cost return, clinical revenues) under the control of the director for the center.
- Formal codification in institutional policy of:
    - The organizational status of the cancer center and authority of the center director as comparable or superior to that of departments and department chairs.
    - Reporting structures.
    - Responsibility of other institutional leaders (deans, hospital presidents, and department chairs) to ensure cross departmental integration and long-term stability of the center, and to support cancer center objectives, including access to clinical inpatient and outpatient facilities and joint oversight of faculty critical to linking oncology care and research.
    - A well-defined plan for a change in directorship and for institutional commitment to continuing support of the cancer center.

This section of your application should describe the institutional commitment to the center, including its recognition and status as a formal organizational component; the provision of space, positions and discretionary resources; the authorities of the director; the status of the director in comparison to departmental chairs; reporting structures; responsibilities of institutional leaders to ensure the long-term stability of the center; and a plan for assuring continued commitment of the center in the event of a change in directorship.

Include a letter signed by the Dean and Hospital President or other appropriate institutional officials documenting specifics of institutional commitment both for the long term future of the center and for this award period.

The stability of a consortium should be demonstrated via provisions of formal written agreements, as well as the history of collaborative research activity, and the contribution of each consortium institution to the cancer center. A copy of this agreement should be included with the application.

Center Director: The director should be a highly qualified scientist and administrator with leadership experience and institutional authority appropriate to manage the center, whether it is a small institution or a highly complex consortium. The director should serve the center on a full-time or a significant part-time basis, and should have the following authorities:

- A senior position (within a matrix center, at least equivalent to a Departmental chair), with appointments to decision making committees relevant to the cancer center and formally codified authorities.
- Control of faculty appointments to the cancer center, and of their periodic review for continued membership (i.e. ultimate authority for determining which individuals will be productive, contributing members of the cancer center).

- At a minimum, joint control (for example, with a department chairman) of recruitments of individuals who are to be members of the cancer center.
- Full or shared control of specific research and resource space and equipment dedicated to the cancer center; this control provides the independent flexibility to enhance and develop the research capability and resource needs of the center.
- If conducting clinical research, sufficient authority of the center director or designee over inpatient and outpatient facilities to achieve center clinical research objectives, and over the appointment and performance of individuals critical to linking oncology care to clinical research.
- Control of philanthropic funds donated to the cancer center.

In your application, describe the qualifications of the center director in relation to scientific background and leadership experience and his/her time commitment to the center. Describe the status of the center director within the institution; any appointments to decision-making committees relevant to the cancer center; and authorities in relation to integration of research across schools and departments, appointment and review of Program members, recruitments and faculty positions, research and resource space and equipment dedicated to the center, revenue streams, and inpatient and outpatient facilities.

Consortium centers should include a discussion of the authorities of the center director over CCSG-supported resources in collaborating institutions and the integration of scientists from consortium institutions into the formal scientific Programs of the center.

7.0 Descriptions, Budgets, and Narrative Justifications for Individual CCSG Components

Using the forms and instructions in the PHS Form 398 (rev.06/09), for each allowable budget category for which funds are requested, prepare:

- A description
- A budget for the First 12 month Budget Period
- A summary budget for the Entire Proposed Project Period

Do not provide narrative justifications for individual Program leaders, since this information is already included in the *Research Programs* section of the application. Include a simple consolidated budget for Program leaders.

The CCSG is intended to provide reasonable costs for a great variety of activities that are clearly related to the research needs of the cancer center. The narrative describing the role and function of requested personnel should clearly justify the stated percent effort, whether or not salary is requested. The major categories of allowable costs include the following:

7.1 Senior Leadership: No more than 1 page per senior leader, plus 1 additional page for discussion of their collaborative activities. Prepare a description and a consolidated budget of percent efforts for all senior leaders and narrative justifications that carefully describe their roles. Each narrative should be followed by a biographical sketch (see PHS Form 398 rev. 06/09).

Individuals in pivotal leadership positions in the center are eligible for salary support for the time and effort they devote to its research activities. They should be in place and committed to a defined percent effort commensurate with duties and responsibilities. Applicants and reviewers should consider the breadth and complexity of the role of each senior leader and determine the appropriate level of effort needed to meet this responsibility. Requests should not be based on any perception that reviewers expect a standard level of effort for all senior leaders.

7.2 Leaders of Scientific Research Programs: Budget pages only. Provide only a single consolidated budget that lists all Program leaders in the center and their percent efforts. This is merely a consolidation of the separate budgets provided and justified in 7.0. Do NOT provide any narratives.

7.3 Staff Investigators: No more than 1 page per Staff Investigator. The P30 Cancer Center Support Grant Guidelines state that members of the center who are clearly important contributors to the programmatic or translational activities of the center may receive salary from the Staff Investigator budget for their specific roles in the center.

Research Staff Investigators must be a Principal Investigator on at least one NCI approved peer-reviewed and funded research-project award. Peer review of Research Staff Investigator candidates includes their research track record, their special importance to the center, and whether their budget allocation is commensurate with the time and effort for activities not supported by other awards.

For Clinical Staff Investigators, peer review criteria include their contributions to development and implementation of the center's clinical activity, including authorship of clinical trials, accrual of patients on interventional trials, or leadership roles in cooperative group studies, and whether their budget allocation is commensurate with the time and effort devoted to these activities.

The Guidelines do not prohibit members with other official roles in the Center from receiving additional support as a Staff Investigator; however, responsibilities for each role should be clearly distinguished. The duties associated with that of a Program Leader, for example, include fostering transdisciplinary, inter- and intra-programmatic interactions relevant to programmatic research goals. Effective Program Leaders provide stimulation, focus, and direction which enhance individual productivity of scientists and result in productive collaborations within and between programs. An additional role as Staff Investigator for a Program Leader should be distinct and clearly justified by separate functions.

Prepare an overall description for the component, and a consolidated budget. While there is no limit to the number of Staff Investigators that may be requested, choices should be made judiciously and clearly justified by the description of duties. Provide a separate narrative justification, with a detailed description of duties, and a biographical sketch for each Staff Investigator. The narrative should specify the category of Staff Investigator, the formal research Program(s) of the Center in which the Staff Investigator participates, and other information pertinent to the request (e.g., for Research Staff Investigators, a list of peer reviewed grants on which they serve as Principal or Co-Investigator; for Clinical Staff Investigators, a list of authored trials, etc).

7.4 Planning and Evaluation: No more than 5 pages. Provide an overall description, a consolidated budget, and a narrative justification for each planning and evaluation activity. The narrative should summarize how past CCSG funds were used, what was accomplished to improve and develop the cancer center, and how future needs will be met with the requested budget. While budgetary support for development of future scientific

Programs is not allowable in the CCSG, plans for developing such Programs should be included in this section. Include a consolidated list of the individuals comprising the External Advisory Board, with titles and institutional affiliations, and attach their biographical sketches. Discuss recommendations made by the external advisory group, any actions taken in response to those recommendations, or reasons for not responding. Present the center's planning and evaluation processes, in this and other relevant sections of the application. No separate, written strategic plan is required.

Costs of planning and evaluation might, for example, include support for a well-qualified external advisory committee; the use of ad hoc scientific and technical consultants when appropriate; a seminar series, when the speakers or invited participants clearly serve as consultants for the Center's scientific or administrative activities, as documented by agendas and/or written evaluations; retreats designed to stimulate transdisciplinary research opportunities; and the conduct of regular assessments of research progress, interactions, membership participation, etc. by the senior leadership of the center. Use of Developmental Funds (see below) should be guided by the priorities and opportunities identified through the planning and evaluation activities of the center.

7.5 Developmental Funds: No more than 12 pages. Prepare an overall description and a composite budget that includes all developmental fund categories being requested and explain how they will be linked to the strategic and programmatic priorities and scientific opportunities of the center. Also provide individual budgets by category with separate narrative justifications. Narratives should summarize how past CCSG developmental funds were used, what was accomplished with them (e.g., establishment of a new shared resource, number of recruitments and areas of expertise, number of pilot projects resulting in peer-reviewed funding, etc) and how the new request will be used to meet the center's strategic goals. If pilot projects are proposed, describe how the projects are reviewed for scientific merit and selected for funding.

Developmental Funds are the major source of budgetary flexibility in the CCSG and should be linked substantially to the planning and evaluation activities of the center. These funds allow centers to take risks; strengthen weaker scientific areas; and provide scientists the opportunity to explore innovative ideas, new collaborations and new technologies. This request category has no dollar limit or limit on the percent of the total CCSG budget.

The cancer center must centrally monitor and evaluate the effectiveness of all developmental funds. These funds can be administered flexibly--dispensed centrally by the director and senior leaders to achieve broad strategic objectives or be delegated to individual Program leaders to target specific scientific objectives. The latter approach has proven to be very successful for many cancer centers.

Maintain careful records on allocation of developmental funds, the rationale for their use, and their effectiveness. Developmental funds may not pay for training, routine equipment purchases or upgrades for established shared resources, or salary support for Program leaders. They should not be used to cover costs associated with the recruitment process itself or for large equipment purchases associated with recruitment packages.

Developmental funds may be used *only* for the following:

To recruit faculty level scientists in areas of strategic need: Judicious recruitments strengthen weak areas of science and enhance the center's overall research strength. Eligible investigators therefore are: (1) those newly recruited from outside the parent institution, with developmental support beginning at the time of, or very soon

after, arrival at the grantee institution. (2) those inside the institution who, whether junior scientists or well established in other scientific areas, are entering the field of cancer research as independent investigators for the first time.

Developmental funds may not be used to support training or tuition costs, but may fund recruitment packages that include the staff needed (e.g., technicians, graduate students, postdoctoral fellows) to initiate the research program of a new investigator. The duration of support from these funds should not exceed 3 years. This category should provide temporary support permitting a new cancer investigator to establish his/her scientific activities at the new center and achieve independent funding. Developmental funds cannot support established cancer researchers already within the institution (e.g., principal investigators on NCI supported R01s or subproject leaders on P01 or P50 multicomponent grants).

In your application, explain how these developmental funds were used in the previous 3 to 5 year grant period, specifying which investigators and projects were supported, the rationale for recruiting these investigators relative to the needs of the center, and to what extent these investigators were subsequently productive as evidenced by research grants and publications.

Identify the kinds of individuals the center plans to recruit as part of its future plans for developing the center. Identification of particular individuals or research plans is not necessary.

Interim salary and research support: The center director may provide partial support for up to 18 months to an investigator who has a reasonable probability of regaining independent research support in the near future. Interim salary and support is independent of any salary funded by the CCSG in the Staff Investigator category. Individuals who are having chronic difficulty with peer-reviewed grant support, and for whom permanent institutional funds are not available, are ineligible.

Your application should include a description of the process and the criteria used to select investigators for interim support. The use of interim salary and research support must be reported to NCI in each non-competing continuation application. Peer review at the next competitive evaluation will examine the uses of the interim support category and the success that individuals supported from this category have had in regaining peer-reviewed grant support.

To support pilot projects that allow center scientists to pursue new, innovative, high-risk ideas or stimulate high priority research areas (e.g., translational research): Centers are encouraged to make these funds accessible to all applicable areas of research, including laboratory, clinical, prevention, control, behavioral and population research for projects of relatively short duration (i.e., 1-2 years). Pilot projects may be awarded to either new or established investigators. Developmental funding may be used for pilot projects or feasibility studies preparatory to the development of an application for independent peer-reviewed support, or to take maximum advantage of a unique research opportunity or nurture an innovative idea. Funds may stimulate a high priority research area, explore a new direction for a Program, explore an unconventional hypothesis, or encourage cross-disciplinary translational research. Support of small, hypothesis-driven early clinical trials of an exploratory nature is particularly encouraged.

Your application should describe the processes for eliciting high-quality proposals and review of scientific merit, and list the awardees and their projects for the preceding project period. Describe the outcome of all projects supported by the CCSG through the pilot-project mechanism (e.g., grant awards, publications, etc.).

- To support technology/methodology development projects: NCI encourages the development of new technologies that will advance cancer research. In these Guidelines, technology refers broadly to methodologies (procedures, instrumentation, analytical tools or reagents) that address important problems in cancer research, including, but not limited to, areas such as the detection and analysis of molecular signatures of cancer in vitro or in vivo, biomedical imaging, model development, drug discovery, tumor targeting, drug delivery, survey development, and informatics.

- Funds for technology development projects can be awarded through an internal review process to resource leaders and individual cancer center scientists. Review criteria should emphasize scientific merit, innovation, and the likely impact of success on important areas of cancer research. If CCSG resources are used in partnership with industrial resources, the cancer center must assure that applicable federal law governs the public availability of any final products of the research.

- Development of new shared resources and novel components in existing shared resources: Developmental funds may be used to help develop new shared resources or new and unique components in existing shared resources whenever the center recognizes the need. If the resources are sufficiently developed to be proposed and reviewed as established resources, they should be proposed under the shared resources category. New and unique components for existing shared resources may also be supported, but must be fully justified.

7.6 Cancer Center Administration: No more than 12 pages. Provide a description, budget and narrative justification. Limit the administrative budget request and narrative justification to the specialized research needs of the center. Include the costs necessary for central administration of resources and services required for center research activities, fiscal management of the center, and reporting activities. Because administrative structures differ from center to center, carefully explain and justify requested support.

The CCSG central administrative budget may support an appropriate percentage of the salary of the chief administrator, secretarial and other staff, travel needs of senior leaders and Program leaders in the performance of their center-specific roles, and supplies for the administrative functions of the center. Funding for a percentage of salary for a staff person to support links with state health departments, other state agencies, or the Centers for Disease Control and Prevention (CDC) is allowable, as well.

Examples of non-allowable costs include non-research educational activities, public relations, fund-raising, and grant application and manuscript preparation. Matrix centers should not duplicate parent institution responsibilities i.e. services normally supported through indirect costs or functions and services the institution normally provides to other comparable research units of the institution (e.g., departments).

Describe the:

- Role of individual administrative staff and their specific responsibilities, including staffing and other support for the administrative office provided by the CCSG and other funding sources

- Funds committed to the center by the institution, including amount, source (e.g., separate return of indirect costs, endowment income, clinical income, or other support), and use (including processes for determining how funds will be used).

- Role of the center within the institution, including relationships with the central grants office of the parent institution (e.g., level of support and overlap of functions) and with clinical entities (e.g., inpatient, outpatient, and networks), and other pertinent entities.
- Decision making processes at the center and the role of administration.
- Policies regarding:
    - Use of cancer center space.
    - Grant submission procedures and the subsequent effect on budgeting and indirect cost return
    - Shared resources, including center oversight, prioritization process, prices, chargebacks, subsidies or differential charges, auditing, user satisfaction measures, and quality control.
    - Administration's role in support of
        - Faculty recruitment processes, including cooperative efforts with academic departments in recruiting faculty, funding salaries, and conducting tenure reviews
        - Space management, including policies on assignment and retention
        - Membership application processes, including policies on appointment and removal
        - Arranging and documenting meetings organized by the center
        - Management of philanthropic funds
        - Processes for solicitation, receipt, review, award, and monitoring of pilot projects
        - Budgeting processes and responsibilities for accounting and expenditure monitoring
        - Purchasing processes

8.0 Research Programs

8.1 Goals: Cancer centers foster cancer-focused research, in part through the creation of formal scientific Programs. A Program comprises the activities of a group of investigators who share common scientific interests and goals and participate in competitively funded research. Programs should be highly interactive and lead to exchange of information, experimental techniques, and ideas that enhance the individual productivity of scientists and often result in collaborations and joint publications. Ultimately, the success of Programs is measured by scientific excellence and the emergence of productive collaborations. How this is achieved will vary with the center and the needs of particular Programs. Formal or informal planning meetings, seminars and retreats, developmental funding of selected pilot projects, new shared resources or key recruitments may be effective ways of promoting increasing levels of interaction.

8.2 S**election of members** of a center's Programs is one of the most critical decisions made by leadership. Functional and productive Programs select individuals for their scientific excellence and, just as importantly,

for their commitment to work together to further the scientific goals of the cancer center. Program members may contribute in any of the four missions of the cancer center - research, education, dissemination, and clinical investigations. Some Program members may not necessarily hold peer-reviewed grants, but may contribute to the research objectives of the center in other important ways and their contributions should be recognized. ***Clinical investigators may be eligible for CCSG funding as Clinical Staff Investigators.***

Many Programs in cancer centers involve sustained collaborations with scientists who clearly strengthen and enhance value-added interactions and the scientific productivity of the research but who have no formal appointment within the institutions that comprise the cancer center. Collaborators from other NCI- designated Cancer Centers or research institutions may become center and Program members. While the funded research projects of these members cannot count toward the funding base of the Program, these members may have full access to shared resources and developmental funds.

8.3 Characteristics of Programs: Programs should be of adequate size and scientific quality, should exhibit a high degree of interaction, and should be capably led. A Program must have at least 3 peer-reviewed and funded research projects (e.g., % R011 + % R012 + % R013 = 300%) from a minimum of 3 separate, independent principal investigators. Peer-reviewed, funded research sub-projects of larger grants (e.g., P01s, P50s) may be counted as separate projects, but not cores.

The interactive attributes of a Program are documented most convincingly by collaborative research projects and joint publications. Colloquia, joint seminar series, and other evidence of meaningful interchange serve to cement interactions around related or common goals. In addition, effective leadership provides intellectual stimulation, cohesion, focus, and direction.

8.4 Definition of Peer-Reviewed, Funded Research Projects for Inclusion in Programs and for Designation of Users in Cores: Peer review as employed by the NIH is the acceptable standard for inclusion of a cancer-related research project within a formal Program. Peer-reviewed, funded projects include the following:

- Awarded individual research grants, cooperative agreements and research contracts from the NCI including all awards with the following prefixes: R01, R03, R18, R21, R24, R25E, R29, R33, R35, R37, R41, R42, R43, R44, R55, P01 and P50 sub-projects, P30s other than the CCSG, U01, U54, U56, N01 research contracts and peer-reviewed, funded subcontracts of center members participating in collaborative research. (Note: Shared resources/cores of multi-component grants are not eligible for inclusion.)

- Components of National Cooperative Groups (e.g., U10s, U19s) funded by the NCI

- Individual research studies involving protocols approved by the NCI Cancer Therapy Evaluation Program (CTEP) and funded by NCI.

- Individual research studies involving prevention and control protocols approved by the NCI Cancer Control Protocol Review Committee and funded by NCI.

- Awarded research grants, cooperative agreements, and research contracts from other institutes of the NIH (same prefixes as above).

Awarded *research* grants from the following organizations also qualify for inclusion:

Agency for Health Care Research and Quality (AHRQ)

American Foundation for AIDS Research (AFAR)

American Cancer Society (ACS): national office only

American Institute for Cancer Research (AICR)

Prevent Cancer Foundation

Centers for Disease Control and Prevention (CDC)
Central Office of the Veterans Administration (VA): Excluding local/ regional awards and "block" grants

Environmental Protection Agency (EPA)

Food and Drug Administration (FDA) Howard Hughes Foundation

Leukemia and Lymphoma Society Multiple Myeloma Research Foundation

National Institute for Occupational Safety and Health National Science Foundation

Susan G. Komen for the Cure

US Army (DOD) special research programs
in Ovarian, breast, and prostate cancer

University of California – wide Breast Cancer Research Florida Biomedical Research Program
Programs

University of California – wide Tobacco Related Disease Research Program

If a center has individual funding from an agency not listed above, they may request that the agency receive peer review consideration. It is inappropriate to predicate programmatic eligibility or scientific breadth and depth on funding of this nature, however. Instructions and application forms for requesting peer review consideration of selected individual cancer research grants from a source not listed above may be found at http://cancercenters.cancer.gov/documents/fundorg.pdf.

Submit 5 copies of the form to the address below *by the time of CCSG application*:

Referral Officer
National Cancer Institute
6116 Executive Boulevard, Room 8041, MSC 8329
Bethesda, Maryland 20892-8329 (for Express mail use Rockville, MD 20852)
Tel: 301/496-3428

Fax: 301/402-0275

8.5 Formatting For Each Program Section: Limit of 30 pages per Program on average, excluding title page, biosketches, budget, budget justification, and lists of funded projects, clinical trials, and publications. Centers that include most or all clinical research in one Program may exceed the page limitation for this Program only.

Title page of the Program with the name(s) of the Program leader(s) and the Program code (used in Summaries 1 and 2 of the Standard Cancer Center Information Summaries).

A description of the Program using page 2 of the PHS Form 398 (rev. 06/09), including:

The central themes and scientific goals of the Program.

The number of Program members and the number of departments and schools represented.

The NCI and other peer reviewed cancer-relevant support for the last budget year.

The total number of publications and the percentage of intra-programmatic and inter-programmatic publications in the last grant period.

A **budget** for the percent effort of the first and future years for the Program leader(s) using the standard budget pages provided in the PHS Form 398 (rev. 06/09). A level of effort must be included for each Program leader whether or not salary is requested. Indicate if salaries meet or exceed the NIH salary cap.

A **budget narrative justification** based on the specific role of the Program leader(s) in facilitating the discovery process and promoting transdisciplinary research important to cancer.

Biographical sketches of Program leaders(s) Use the PHS Form 398 (rev. 06/09). Note that the form includes information on positions and honors, selected peer-reviewed publications, and research support. Information on other support beyond that required in the biosketch should NOT be submitted with the application.

A list of the **externally funded research projects (no page limit)** of the Program separated into two categories: **"peer-reviewed"** and **"non peer reviewed"** by member, project and funding source, using the format described for Summary 2A. **Program leaders should exclude grants focusing on other diseases (e.g., diabetes, cardiology, Alzheimer's disease) or address their cancer relevance in the programmatic description** -- particularly for Program members whose peer-reviewed funding includes **only** grants in other diseases.

If applicable, a list of the **clinical research (no page limit)** of the Program, using the definitions and sort order specified in the instructions for Summary 4.

The **members** of the Program in alphabetical order, with their departmental and institutional affiliation, their academic rank (or equivalent) and their role in the Program (e.g. researcher, clinician placing patients on clinical trials). Highlight any members of the Program who are proposed as Staff Investigators by indicating for each person the percent effort for which CCSG salary support is being requested.

The **scientific goals** of the Program and how the interests, expertise, and research approaches of the Program members facilitate their achievement.

The most significant **scientific accomplishments** of the Program within the last 5-year project period and the ways in which the cancer center facilitated or enabled these accomplishments.

For clinical and translational Programs, describe accrual of patients to all types of clinical trials, in relation to the patient population, using the format described for the Clinical Protocol and Data Management Shared Resource (see Section 9.1). A total of 10% accrual to therapeutic and prevention trials constitutes a general benchmark for a reasonable level of protocol accrual. Briefly describe activities that demonstrate leadership, interaction, and collaboration in other NCI-funded clinical programs, such as Cooperative Groups and SPOREs, and in other multi-site clinical networks.

Interactiveness of the Program members with each other and with members of other Programs, as documented by Program agendas (minutes not required) and other activities.

The number of total publications of the Program and the percent that are inter- and intra-programmatic. Report this information in the Program description. Of total publications, 10% inter- and 10% intra-programmatic publications constitute general benchmarks for a reasonably interactive Program. Publications should represent the broad diversity of Program members.

A ***selected*** list of Program-related publications **(no page limit)** from the last project period. Indicate those that particularly illustrate the inter- and intra-programmatic collaborations.

9.0 Shared Resources and Other Support Elements: No more than 12 pages per resource, excluding usage tables

The CCSG may pay for fixed costs associated with centralized shared resources and services. These costs are not directly identified with specific research grants. (With the exception of Protocol Specific Research Support and Developmental Funds for pilot projects, CCSG funds do not support project-specific research activities, which are paid for by research project grants.)

NCI recognizes that virtually all shared resources derive a portion of their operating costs from multiple sources. These guidelines therefore apply only to the proportion of the shared resource that is paid for by the CCSG.

9.1 Shared Resources provide access to technologies, services, and scientific consultation that enhance scientific interaction and productivity. The support of shared services for an entire center provides stability, reliability, cost-effectiveness, access to specialized technology and methodology, and quality control.

The primary users of shared resources and services are cancer center members with peer-reviewed, funded projects, a standard assuring CCSG funds support high-quality research. Access by others is at the discretion of the center director and should be justified by contributions to the overall cancer research objectives of the center (e.g., access by a junior investigator funded by a pilot project).

Although demand and level of usage are important in evaluating requests for CCSG support of shared resources, certain technically sophisticated resources are critical to a center’s research progress (e.g., x-ray crystallography, preparation of clinical grade gene therapy vectors, proteomics, family ascertainment, health

communication, tracking, nutrition support) but are not adaptable to high-volume operation or will have a few very specialized users. Such resources are judged for scientific value, the needs of past and potential new users, accessibility to cancer center members, and the effectiveness and fairness of the process for setting scientific priorities for their use. Shared resources should never be established for exclusive or primary use by one or two members only, however.

Support Resources Not Typically Supported by Charge backs to Research Grant Mechanisms: Some types of shared resources, such as biostatistics, informatics, and clinical protocol and data management, provide crucial services that are not typically supported by charge backs to research grant mechanisms. Usage criteria by funded investigators are not applicable to these shared resources. Clinical trials cores certainly accept patient registrations onto clinical trials by non-funded cancer center members. Biostatistics reviews all clinical trials and collaborates in developing new grant applications by as yet unfunded investigators.

Possible Shared Resources: A center proposes those functions that it wishes to have funded as shared resources, but then must defend its choices and the associated budget request at peer review. A center is not limited to the list of examples of potential shared resources below supporting laboratory, clinical, and prevention/control/population sciences:

Centralized equipment; general and specialized animal colonies; specialized instrument shops; nucleic acid sequencing/synthesis labs; amino acid analysis HPLC facilities; cell sorting; chemical and drug synthesis labs; mass spectrometry labs; electron microscope facilities; media preparation; microarrays and proteomics facilities and services.

Histology and pathology services; tissue culture; tumor procurement service; immunology or immunoparameters testing facilities; radioisotope facilities; experimental radiation facilities and services; clinical data management and protocol tracking for clinical trials.

Biostatistics; imaging; clinical and population science economic analysis units; research-related informatics; other biospecimen (e.g., serum) procurement services; clinical and population science measurement units; survey research facilities; intervention, recruitment or dissemination shared resources; high-risk family registries.

Centers present resource requests in various ways. Some prefer to group several shared resource components into a single categorical request (e.g., Immunology, Cell Biology).

Budgets: In general, the CCSG provides salary stability for some of the “fixed” costs associated with key personnel operating the resource and providing consultative services, as well as minimal supplies; “variable” costs are usually supported by user fees or by other sources. Costs will depend upon the frequency of use of the resource, as some resources will be more self-sustaining than others and will cost the CCSG less, and also upon whether the service is a support function (e.g., glass washing, media preparation), or whether it provides access to expertise and technology (e.g., DNA sequencing, transgenic mice), or to collaboration (e.g., biostatistics).

Operational Costs to the CCSG: Because special considerations depend upon the characteristics of the institution (the technical or non-technical nature of the resource, and the proportion of the resource paid for by sources other than the CCSG), no standard approach applies to all shared resources and services. Since the

primary costs of research are supported by the peer-reviewed, funded grants and research contracts of the center, consider the following elements in developing budgets for shared resources and services:

Need for the resource relative to current and future peer-reviewed research activities of the center

Current and projected use of the resource by multiple investigators

Cost-efficiency, particularly in comparison to other options (e.g., purchase orders or contracts to an outside vendor)

Stability of the operation and quality of the service

Accessibility of the resource or service to qualified member-investigators, including the critical consultative role performed by experts who direct selected shared resources.

Proportion of the total resource operation paid for by the CCSG relative to other sources.

National Institutes of Health (NIH) Policy Relative to Program Income: As with all other grants issued by the NIH, if income is realized from grant-supported activities (e.g., from CCSG supported shared resources), this income must be reported in the budget/financial statements accompanying annual progress reports and on the annual financial status report. In accordance with NIH Grants Policy, the "additive cost alternative" will apply to the first $25,000 of program income. Unless approved for use otherwise, program income in excess of $25,000 will be deducted from the next year's award.

Formatting: The 12-page limitation, excluding capacity and usage tables, is intended to accommodate bundled requests of this kind. Requests for most individual shared resources should require much less than the 12-page limit.

Prepare appropriate description, budget information, data and narrative justifications for each resource.

For institutionally managed (as opposed to cancer center managed) resources, describe the center role in setting priorities, resource planning and oversight, as well as priority access established for center members.

Present all shared resources critical to the clinical research needs of the center (e.g., biostatistics, centralized protocol management office) last, so they can be reviewed in sequence with the next sections, "Protocol Review and Monitoring System", "Protocol-specific Research Support", "Data and Safety Monitoring", and Data Sharing.

In the narrative for each shared resource, describe the:

Services and technologies provided and their importance to the scientific needs and objectives of the center.

Qualifications of the resource director(s) and the competence of key technical staff; include a biosketch of the resource director(s) and manager(s).

Center's policies on operation and use of the shared resource, e.g., access, priorities, limits (e.g., hours of operation, staffing, etc.), and charge back systems.

Cost-effectiveness of the resource relative to other options for obtaining the service, such as outside vendors, when applicable, and the approach used to evaluate the current extent of use by peer-reviewed, funded center investigators, and projected increase in use, if applicable, based on the scientific needs of the center.

Record keeping: Maintain user logs for each shared resource/ service and have them available at the site visit.

Shared Resource Data Format: Provide the following data in the application:

Current grant year reporting period: Choose one

_____ January 1 to December 31: 20??
_____ July 1 to June 30: 20??-??
_____ Grant year: provide inclusive dates

This shared resource is:

_____ Cancer center-managed
_____ institutionally-managed
_____ jointly managed
_____ other (Explain)

Total Operating Budget: The requested budget should reflect realistic needs in terms of support from other sources (e.g., institutional support or recovery from chargeback); recent past utilization by the scientists accessing the resource, anticipated future increases in usage, and any other specific additional requirements. Provide the following information for the most current grant year and for the proposed period of support.

Income Source	Current Support ($)	Percent of Current Total Budget	Proposed Support - Year 1 ($)	Percent of Proposed Total Budget
CCSG				
Other				
Charge backs				
Institutional support				
Other sources				
Total Operating Budget				

Capacity of Resource (no page limit): List the major services provided by the shared resource, indicating and defining an appropriate unit of measure (number of samples, hours of technical or professional times, etc.) for each **major** service provided (e.g., number of nucleotides sequenced, # of samples processed, etc.); services can be clustered, where appropriate. For each service indicate the total capacity per year based on your current equipment, staffing, space, and available work hours. Do **not** include this table for the support resources described above.

Name of Service	Unit of Measure	Definition of Unit of Measure	Total Capacity /reporting 12 month period
DNA sequencing	# of samples	Number of samples, sequences, etc.	

Shared Resource Use (no page limit): For each service listed in the table above, provide the total number of users in each category, the total units used for investigators in each category, and the percent of the total resource capacity that is used by each category of investigators. For the top 75% of units of use during the reporting period, list the individual user names and scientific Program codes (from Summary 1 B), the units used by each investigator, and the percent of the total resource capacity this represents. A suggested format for this table is found below.

Category of Users	Scientific Program Code(s)	# of users in this category	# Units used	% of Total Capacity or usage
Center members with any active peer–reviewed research funding during the reporting period				
Member name				
Center members with no active peer-reviewed research funding during the reporting period				
Member name				
Non-center members (number only)				
Last 25% of users				25%
Total				100%

Specific issues regarding certain shared resources:

Informatics: Scientific progress depends increasingly on the management, sharing, and analysis of data from diverse sources. In cancer centers, informatics expertise and resources are critical shared resource functions. The CCSG may support applications of informatics directed toward cancer research (including the acquisition, maintenance, and integration of database systems for clinical trials or studies in populations; data extraction, storage, and analysis tools for genomics, proteomics, or molecular structure; a database annotating a research repository involving human specimens; and tools that enable sharing of data sets with collaborating investigators in related areas of research). Performance of specific research functions, such as data entry, for individual research projects or clinical trials is excluded.

As the interoperability of independently developed informatics systems is an important goal of the research community, informatics development efforts supported by CCSG funds must be in compliance with evolving standards articulated by the NCI, the scientific community, and other standard-setting organizations in the medical and bioinformatics areas.

Dissemination Shared Resource: While all cancers centers are expected to share lessons learned from the center's research with the wider scientific, public health, and clinical practice communities and the public, some centers may elect to support a shared resource to support dissemination *research*.

In your application, describe the contributions of the shared resource to planning and evaluation of development-to-delivery activities of the cancer center. Describe market analytical, needs assessment, communication and other relevant dissemination analytical capabilities, the number of investigators and Programs making use of the resource, the audiences to whom research findings are being disseminated and the expertise of the *research* personnel dedicated to this task. Describe the level of staff expertise in market research, audience analysis, communications science as well as resources to systematically assess target audiences preferences for cancer information, etc. More information about NCI's research diffusion and dissemination programs can be found at NCI's web site: http://cancercontrol.cancer.gov/d4d/**.**

Imaging Shared Resource: Imaging plays an increasingly important role in cancer clinical trials. New functional, molecular imaging methods require rigorous attention to standardization and quality assurance issues. Most imaging is acquired in digital format, allowing the information to be archived and processed in a variety of ways (e.g., volumetric measurements and computer-aided algorithms for detection and analysis of lesions are possible). The budget for a shared resource for imaging could include dedicated equipment for imaging in clinical trials, imaging expertise for protocol development and quality control, computer hardware and software for the acquisition, analysis, integration and archiving of research image data, and personnel to support these functions. It also might include partial salary support of a radiologist or other imaging expert for expert consultation in planning cancer center research projects or clinical protocols and analyses for publication or required software.

Describe the location of the facility relative to center users, and availability of space at each location for experimental set-up. Provide specific examples of how the shared service has facilitated the initiation of imaging projects for novice users. Provide current and anticipated cancer-related research use, relative to the total use of the facility, the recharge rates for animal and clinical scanners, and recharge rates for funded projects without imaging budgets.

Biostatistics: Biostatistics is a shared resource central to the mission of most centers, particularly those that perform clinical or population research. Participation by statisticians in many collaborative activities of the cancer center is eligible for CCSG support. Salary support is allowable for participation in cancer-center pilot projects, assistance to center investigators in conceptualizing and developing research projects, analyses for publication, and the development of methodology that is clearly and closely related to the support of specific projects within the cancer center. The CCSG is not intended to support independent, investigator-initiated research in statistical methodology, for which statisticians, like other scientists, should be supported by project-specific grants. Nor is it typically intended to support a significant collaborative role on a funded research project, since the statistician would normally be supported by an appropriate time-and-effort allocation as a

collaborator on that grant. CCSG support may be particularly useful for unanticipated needs for statistical collaboration arising in the center.

Clinical Protocol and Data Management Shared Resource: This resource provides central management and oversight functions for coordinating, facilitating, and reporting on, the cancer clinical trials of the institution(s) that define the center, whatever the study origin (local, industrial, cooperative group, or other). As a tool for management of a center's clinical research program, it complements the Protocol Review and Monitoring System. This resource provides a central location for cancer protocols, a centralized database of protocol-specific data, an updated list of currently active protocols for use by center investigators, and status reports of protocols. Quality control functions might include centralized education and training services for data managers and nurses, and data auditing. Data and safety monitoring functions are typically located within this shared resource. Centers with complex clinical trials programs might choose to split these functions into separate resources.

The resource allows oversight and quality control for the center's entire clinical trials effort *but does not include tasks involved in the actual direct conduct of individual trials (such as data entry)*. Therefore, the CCSG request for this resource should not duplicate, replace, or make up for reductions in funding provided through the individual grants and contracts supporting the studies.

Peer evaluation of the request for CCSG support is based on the quality of the management and oversight functions performed (i.e., system or method and procedures, not individual patient files) and the quality and diversity of the center's clinical trials effort.

The following table is helpful in providing reviewers with an overview of clinical trials accrual over the five year project period preceding the competing renewal application. As it is a summary of Standard Cancer Center Summary 4 data, definitions used in Summary 4 apply to the data in this table. The form is intended as a template only and may be adapted to fit a center's individual needs.

Grant funding year	1	2	3	4	Total
Calendar year	200?	200?	200?	200?	Total
Accrual to Intervention Clinical Protocols By Sponsor (Note: This correlates with the first 2 items[2] under 'Clinical Research Category' in Standard Cancer Center Summary 4)					
National Group					
External Peer Review					
Institutional (investigator initiated)					
Industry					
Total intervention accrual					
% of subjects on institutional studies					
Total accrual at primary institution					
Total accrual at affiliate sites					
Accrual to Non-Intervention Clinical Studies by Sponsor (Note: This correlates with the last 2 items[3] under 'Clinical Research Category' in Standard Cancer Center Summary 4)					
National Group					
External Peer Review					
Institutional (investigator-initiated)					
Industry					
Total non-intervention accrual					
Total of all accrual					

9.2 Protocol Review & Monitoring System (PRMS): **Limited to 10 pages exclusive of protocol listing.** A particularly important function for centers involved in clinical research is a mechanism for assuring adequate internal oversight of the scientific aspects of all the cancer clinical trials in the institution or institutions that formally comprise the center (i.e., consortium centers should document that all protocols are reviewed through a central PRMS). This function is complementary to that of an Institutional Review Board (IRB), which focuses on the protection of human subjects.

[2] Clinical trials involving an agent or device or clinical trials involving other types of interventions (e.g. behavioral modification, nutritional protocols, etc.)

[3] Epidemiologic or other observational studies or companion, ancillary, or correlative studies associated with a clinical trial or other biological studies using clinical specimens that can be linked to patient data.

The PRMS is not intended to duplicate or overlap the responsibilities of the IRB. Auditing, for either quality control or safety reasons, is **not** a function of the PRMS. DSM committee functions and PRMS committee functions are separate and distinct from one another and should not overlap. The focus of the PRMS is on *scientific merit, priorities, and progress* of the clinical protocol research of the center. The PRMS should have the authority to open protocols that meet the scientific merit and scientific priorities of the center and to close protocols that do not demonstrate scientific progress. Quality control concerns are not reflected in the evaluation of the PRMS, unless the problem is so serious as to make the results of the protocols meaningless.

With regard to scientific merit evaluation, the PRMS is expected to evaluate all cancer center trials, whether derived and supported from institutional sources or from industry. **However, the PRMS is not required to duplicate traditional peer review, which includes peer-reviewed protocols supported by the various NIH mechanisms (e.g., R0ls, U0ls, U10s, P0ls, and P50s), other approved agencies listed above, and clinical research protocols approved by the NCI's Cancer Therapy Evaluation Program or the Cancer Control Protocol Review Committee.** These protocols may receive an expedited administrative review for the purpose of prioritization. The PRMS also is *not* required to studies dealing with healthy human subjects and the population sciences, e.g., observational and epidemiologic studies.

All trials evaluated by the PRMS for merit, whether via full or administrative review, have access to CCSG-supported centralized resources, such as protocol and data management, informatics and biostatistics.

Description, Budget, and Justification. Include a description, a budget, and a narrative budget justification. The budget may include appropriate personnel, administrative support, equipment appropriate to the task, and supplies.

Describe the criteria for selection of the membership of the committee. List the members of the committee and their expertise. The biographical sketches of these individuals should be included at the end of this section. Scientific expertise from basic, clinical, and population science/cancer control should be represented on the PRMS committee. While there may be limited overlap, committee representation should not duplicate that of the Data and Safety Monitoring Committee.

Describe the procedures for scientific review and scientific monitoring of cancer clinical trial protocols, including the criteria and process for submission of institutional clinical trial protocols to the committee for review and approval; the process for review of all cancer clinical research protocols of the institution; the review criteria that are used to assess scientific rationale, study design, expected accrual rates, adequacy of biostatistical input and feasibility for completion within a reasonable time period; and the criteria used for monitoring ongoing institutional protocol research to evaluate scientific progress, including reasonable accrual rates, to ensure that the scientific aims of the study can be completed.

Describe the process and criteria used for prioritizing the activation of cancer clinical protocols at the institution with respect to scientific merit and patient availability. Describe the input, if any, of disease focused Programs, to the prioritization process.

Describe the process, criteria, and authority for terminating a clinical protocol. Discuss whether the committee has ever terminated any protocols, and for what reason.

Describe PRMS operations relative to the Institutional Review Board (IRB) approval process with emphasis on the complementarily of the two entities and absence of overlap or duplication.

Provide a list **(no page limit)** of all i**nstitutional protocols** (i.e., studies that have not received external review) that have been reviewed by the PRMS for scientific merit or actively monitored for scientific progress in a recent 12-month period (Grant year, January to December [preferred format], or July through June). Indicate on that list those protocols that were approved and activated, approved but yet activated, deferred for revision, and disapproved.

For activated clinical trial protocols, provide target accruals and accruals to date using the same format provided in Standard Cancer Center Information, Summary 4, Clinical Research Protocol Information on Clinical Research Studies.

Indicate for the same 12-month period how many protocols were monitored for progress and performance and those that were closed, along with the reason for closure. NCI will select a sample of the listed protocols for detailed review prior to the site visit. Do *not* include or append protocols to the CCSG application.

In cases of conditional approval or disapproval of the PRMS, the peer reviewers will clarify in the Summary Statement what steps or changes are needed for full approval, along with any recommendations on timing of re-review by peers.

If the PRMS is conditionally approved, staff of the Office of Cancer Centers will contact the PI by letter to request an application for re-evaluation of the PRMS by the NCI Parent Committee (see Section III below). The letter, with accompanying instructions, will be forwarded approximately four months in advance of the review date recommended by peer reviewers.

If the PRMS is disapproved, a funded grantee may request re-evaluation of the PRMS during the grant project period. Centers interested in re-evaluation should contact their program director for appropriate guidance. Institutional protocols that have not been reviewed by external mechanisms (e.g., CTEP) may not use CCSG-supported shared resources.

The following table is helpful in providing reviewers with an overview of PRMS activity over the five year project period preceding the competing renewal application. In the section entitled ‘Number of New Protocols Reviewed by Sponsor’, each protocol would be counted only once. In the section entitled ‘Number of Protocols’ (shaded in gray), a protocol may be counted multiple times, depending on the number of actions taken on it by the PRMS committee. The form is intended as a template only and may be adapted to fit a center’s individual needs.

Protocol Review and Monitoring System Grant Cycle 200X-200Y

Grant year	1	2	3	4	Total
Calendar year or	20??	20??	20??	20??	
Academic Year	20??-??	20??- ??	20??-??	20??-??	
Number of New Protocols Reviewed By Sponsor:					
National Group					
SWOG					
CCG					
Other					
External Peer Review					
Industry					
Institutional					
Number of Protocols:					
Approved and activated					
Approved but not yet activated					
Deferred for revision					
Disapproved					
Monitored for scientific progress					

9.3 Protocol-Specific Research Support: No more than 4 pages. This CCSG component provides support for short term, feasibility (e.g., pre-phase I, pilot) and phase I clinical trials originating from scientific investigators within the cancer center. Preliminary data generated from these trials, which historically have been only rarely funded through other mechanisms, can be used as the basis for support of later phase trials through competitive grant applications or industry. Criteria for support are as follows:

- Trials should be high priority, innovative, feasibility (i.e., pre phase I, pilot) and phase I institutional clinical interventions focusing on initial early phase testing of a candidate agent or device for the diagnosis, prevention detection or treatment of cancer. Support is not meant for all early phase trials, for later phase trials, or for studies that do that do not involve testing of an agent or device.

- Trials must be conceptualized/designed by members of the center's research Programs.
- Trials should typically be of short duration (e.g., less than one year).
- Trials receiving support through other peer reviewed research grants, cooperative agreements, or contracts are ineligible for support through this mechanism. Trials may receive partial support from industry, assuming all other criteria are met.
- The center's PRMS must be approved or conditionally approved by peer review for funding of positions requested.
- Supported trials must be approved by the PRMS.
- Funding is restricted to support of research nurses and data managers directly involved in the conduct of these trials. No other positions are eligible for support via this component (e.g., pharmacist). Center leadership must oversee these funds (i.e., no funds are allowed for a core director or other supervisory functions).

Provide a listing of all trials supported with PSRS funds, with investigator name, trial name, phase, anatomic site (if applicable), duration, and outcome or impact (e.g., led to peer-reviewed funding for a later phase trial, etc.). Discuss how trials are prioritized for support. Base the budget request on the center's actual and projected clinical trials activity, as well as on complexity of these protocols.

10 Inclusion of Minorities and Women in Clinical Trials (NIH Policy): No more than 6 pages in total, with Inclusion of Children. It is the policy of the NIH that women and members of minority groups and their sub-populations must be included in all NIH-supported clinical research projects unless a clear and compelling justification is provided indicating that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. This policy results from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43). All investigators proposing clinical research should read the "NIH Guidelines for Inclusion of Women and Minorities as Subjects in Clinical Research" (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-001.html); a complete copy of the updated Guidelines is available at http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm.

In your application, provide clear documentation on the accrual of women and minorities into *interventional* clinical trials. If this section of the application is not approved, a grant award *cannot* be issued until a corrective plan and adequate response to the critique is submitted and approved by NCI.

Reviewers evaluating the section of the application on the inclusion of women and minorities in clinical research will consider separately whether the accrual of women and minorities to therapeutic and non-therapeutic trials is proportionate to the cancer patient population in the cancer center's primary catchment area. Thus, separate tables for accrual in therapeutic and nontherapeutic studies should be included (accrual to epidemiologic, outcome, observational and other non-interventional studies should not be included in these tables). Reviewers will assess the total picture, taking **both** therapeutic and non-therapeutic interventional clinical trial accrual into account in relation to approval/disapproval of gender and minority accrual, per the current review criteria in the CCSG Guidelines:

Appropriateness of the accrual of women and minorities to therapeutic and non-therapeutic clinical trials in proportion to the center's catchment area

When accrual is inadequate, adequacy of center's plan to improve performance

When women or minorities are substantially under-represented, the adequacy of the institution's policies, specific activities and a corrective plan become critical in convincing peer reviewers that the institution is serious about addressing the problem and is investing the appropriate effort to correct under-accrual. In addition, if the population of the catchment area of the cancer center has limited ethnic diversity, provide a discussion of the institution's efforts to broaden the ethnic diversity of its clinical trial accrual.

Include the following information in this section:

Demographics. Provide summary information showing the demographics of the primary geographic catchment area of the center by ethnic categories and subcategories and by gender , as well as for the cancer patient population treated at the cancer center.

Accrual. Complete Parts A and B of the "Inclusion Enrollment Report Table", found in the PHS Form (rev 06/09). Provide summary accrual information from the most recent 12-month period by ethnic categories and subcategories and by gender in the following two areas: (a) the therapeutic clinical trials conducted at the cancer center, and (b) the non-therapeutic trials conducted at the cancer center. Relate this information to the demographic information provided above.

Deficiencies and Corrective Actions. If there are any proportional deficiencies in the accrual of women and minorities to therapeutic and non-therapeutic trials relative to the opportunities as defined by the demographics of the center's catchment area, note:

- Any general policies of the **institution** designed to help with this problem
- Unavoidable circumstances that impede accrual of women and minorities (e.g., a high proportion of non-eligible patients)
- Actions planned or being taken by the **center**, based on careful analyses of the population, which demonstrate a clear effort to correct deficiencies that are potentially avoidable.

In addition, the revised PHS Form 398 instructions (rev. 06/09) require applicants to provide data on the composition of *proposed* study populations in terms of gender and racial/ethnic groups. *For CCSG applications, this requirement is limited to projected accrual to phase III studies that utilize CCSG resources and are not funded by any other PHS grant mechanism.* See the PHS Form 398 (rev. 06/09) for table formats for both targeted/planned enrollment and actual enrollment. Please indicate if you have no phase III trials that meet this criterion.

11 Inclusion of Children in Clinical Trials: Included in 6 page limit for Minorities and women, above)
The NIH maintains a policy that children (i.e., individuals under the age of 21) must be included in all clinical research, conducted or supported by the NIH, unless there are scientific and ethical reasons not to include them.

All investigators proposing research involving human subjects should read the "NIH Policy and Guidelines" on the inclusion of children as participants in research involving human subjects (http://grants.nih.gov/grants/funding/children/children.htm).

As part of the scientific and technical merit evaluation of the research plan, reviewers will be instructed to address the adequacy of plans for including children (as appropriate for the scientific goals of the research), or justification for exclusion.

12 Data and Safety Monitoring: **Limit of 5 pages if a budget is requested; otherwise limit of 1 page.** Data and safety monitoring is required for all types of clinical trials, including physiologic toxicity and dose-finding studies (Phase I); efficacy studies (Phase II); efficacy, effectiveness and comparative trials (Phase III). Monitoring should be commensurate with risk. The establishment of data and safety monitoring boards (DSMBs) is required for multi-site clinical trials involving interventions that entail potential risks to the participants ("NIH Policy for Data and Safety Monitoring," *NIH Guide for Grants and Contracts*, http://grants.nih.gov/grants/guide/notice-files/not98-084.html).

Provide a very brief summary of the Center's DSM Plan. Do *not* include the entire DSM Plan within the text but provide a copy at the site visit.

DSM functions are distinct and should not be the direct responsibility of the Protocol Review and Monitoring System (PRMS), which oversees scientific aspects of cancer clinical trials. Do not merge these activities and committees.

By NIH review criteria, the peer reviewers will be responsible for determining whether the plan is acceptable or unacceptable. Peers are expected to define the weaknesses of an unacceptable DSMP and to reflect any weaknesses in the impact/priority score. The final approval of a DSMP in its original form or later modified form is the responsibility of the staff of the Office of Cancer Centers.

If funding is being requested for DSM activities, provide budget and justification pages including:

- A general description of DSM functions, including the workload related to evaluation, auditing, and monitoring of patient safety in institutional investigator-initiated studies and studies supported on competitive grants (e.g., R01s), and the flow and timing of DSM functions for studies, based on phase, level of risk, or other pertinent factors. Do not include DSM activities supported on other grants and contracts.

- A description of the committees involved in DSM processes and the biographical sketches of the members of these committees.

If a budget for DSM functions is not separately distinguished in the CCSG application, it will not be reviewed or funded.

13 Federal Citations Relevant to CCSG Applications (2 pages)

Use of Animals in Research: Recipients of PHS support for activities involving live, vertebrate animals must comply with PHS Policy on Humane Care and Use of Laboratory Animals (http://grants.nih.gov/grants/olaw/references/PHSPolicyLabAnimals.pdf) as mandated by the Health Research

Extension Act of 1985 (http://grants.nih.gov/grants/olaw/references/hrea1985.htm), and the USDA Animal Welfare Regulations (http://www.nal.usda.gov/awic/legislat/usdaleg1.htm) as applicable.

Human Subjects Protection: Federal regulations (45 CFR 46) require that applications and proposals involving human subjects must be evaluated with reference to the risks to the subjects, the adequacy of protection against these risks, the potential benefits of the research to the subjects and others, and the importance of the knowledge gained or to be gained (http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm).

Sharing Research Data: Investigators submitting an NIH application seeking $500,000 or more in direct costs in any single year are expected to include a plan for data sharing or state why this is not possible (http://grants.nih.gov/grants/policy/data_sharing).

You must submit a plan for data sharing if the CCSG provides direct support for the generation or storage of research data (e.g., pilot projects supported through developmental funds, early phase clinical trials conducted with funds from Protocol Specific Research Support) or funds shared resources that serve as the final repository of data (e.g., a high throughput DNA array analysis resource, family registries). If you are requesting a budget for data-sharing activities (e.g., data archiving), include the budget and justification with this section.

. Reviewers assess the adequacy of the proposed data sharing plan, but it is not factored into the determination of scientific merit or impact/priority score.

Policy for Genome-Wide Association Studies (GWAS): NIH is interested in advancing genome-wide association studies (GWAS) to identify common genetic factors that influence health and disease through a centralized GWAS data repository. For the purposes of this policy, a genome-wide association study is defined as any study of genetic variation across the entire human genome that is designed to identify genetic associations with observable traits (such as blood pressure or weight), or the presence or absence of a disease or condition. All applications, regardless of the amount requested, proposing a genome-wide association study are expected to provide a plan for submission of GWAS data to the NIH-designated GWAS data repository, or provide an appropriate explanation why submission to the repository is not possible. Data repository management (submission and access) is governed by the Policy for Sharing of Data Obtained in NIH Supported or Conducted Genome-Wide Association Studies, NIH Guide NOT-OD-07-088. For additional information, see http://grants.nih.gov/grants/gwas/.

Peer reviewers will assess the the adequacy of the proposed GWAS plan, but do not include it in their final impact/priority score.. Concerns regarding GWAS data sharing plans must be resolved by program staff prior to making awards.

Sharing of Model Organisms: NIH is committed to support efforts that encourage sharing of important research resources including the sharing of model organisms for biomedical research (see http://grants.nih.gov/grants/policy/model_organism/index.htm). At the same time the NIH recognizes the rights of grantees and contractors to elect and retain title to subject inventions developed with Federal funding pursuant to the Bayh-Dole Act (see the *NIH Grants Policy Statement)*. Beginning October 1, 2004, all investigators submitting an NIH application or contract proposal are expected to include in the application/proposal a description of a specific plan for sharing and distributing unique model organism research resources generated using NIH funding or state why such sharing is restricted or not possible. This will

permit other researchers to benefit from the resources developed with public funding. The inclusion of a model organism sharing plan is not subject to a cost threshold in any year and is expected to be included in all applications where the development of model organisms is anticipated.

Provide a short description of the center's institutional approach for adhering to the model-sharing policy, as well as specific model sharing plans for any research conducted directly with CCSG funds (i.e., pilot projects conducted with developmental funds) or components serving as research resources (e.g., mouse model and transgenic mouse shared resources , etc.). The adequacy of plans for sharing model organisms will be considered by reviewers when a competing application is evaluated. An assessment of the plan will be provided in an administrative note, but will not affect the overall impact/priority score. If you are requesting a budget for model-sharing activities, include the budget and justification with this section.

Links to Other Federal Citations:

Access to Research Data through the Freedom of Information Act:
http://grants.nih.gov/grants/policy/a110/a110_guidance_dec1999.htm

Required Education on the Protection of Human Subject Participants: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html

NIH Public Access Policy Requirement: http://www.pubmedcentral.nih.gov/;
http://grants.nih.gov/grants/guide/notice-files/NOT-OD-08-033.html; http://publicaccess.nih.gov/

Standards for Privacy of Individually Identifiable Health Information: http://www.hhs.gov/ocr/;
http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-025.html

Authority and Regulations: http://www.cfda.gov/

Healthy People 2010: http://www.health.gov/healthypeople

Loan Repayment Programs: http://www.lrp.nih.gov/

Human Embryonic Stem Cells (hESC): http://stemcells.nih.gov/index.asp;
http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-005.html; http://escr.nih.gov

1**4 Appendices (50 pages):** At the time of submission, two additional copies of the application and all copies of the appendix materials must be sent to the address below.

Referral Officer
Division of Extramural Activities
National Cancer Institute
6116 Executive Boulevard, Room 8041, MSC 8329
Bethesda, MD 20892-8329 (for U.S. postal Service express or regular mail)
Rockville, MD 20852 (for non-USPS delivery)
Telephone: (301) 496-3428
Fax: (301) 402-0275

E-mail: ncirefof@dea.nci.nih.gov

15 Review Materials to be Available At the Full or Limited Site Visit:

- Biographical sketches of all cancer center members. A complete set of biographical sketches facilitates the review particularly if it is available to the Scientific Review Officer for use during the pre-site visit meeting of reviewers

- An updated Summary 2, Active Funded Projects from the Standard Cancer Center Information Summaries, and in the same format, if desired, a *separate* list of grants and contracts *pending* peer review, approval and funding

- An updated a list of the clinical research by scientific Program, where applicable, using the definitions and sort order specified in the instructions for Summary 4.

- Copies of the data to be presented in the posters. Do not send reduced size copies of the full poster as these are not usually easy to read.

- Institutional protocols that have been reviewed by the center's Protocol Review and Monitoring Committee.

- Copies of the minutes or reports of external and internal advisory committees (e.g., the center's Executive Committee), retreats, and other meetings relevant to the planning and evaluation process for the center.

- Log books or other records of use for all shared resources.

- The complete institutional Data and Safety Monitoring Plan.

16 Applications for Comprehensiveness

16.1 First-Stage Review for Comprehensiveness (Scientific Elements): The determination of whether a cancer center will be designated as "comprehensive" (see page 4 for definition) by the NCI is a two-step process. In the first step, peer review determines whether the center fulfills the broad scientific and interactive requirements for comprehensiveness as described elsewhere. Unless a center advises the SRO in advance of the review that they choose not to be considered for comprehensiveness, the Parent Committee will evaluate the scientific and interactive aspects of comprehensiveness as an integral part of the overall review of the Cancer Center Support Grant application.

In consortium centers, a comprehensive designation may be based on research in the primary institution alone, or on supplemental strengths of the research in all consortium institutions. Grants of the partner institutions may be counted toward Program eligibility and calculation of the CCSG/NCI funding ratio, pending a successful peer review.

Questions regarding the comprehensiveness review should be directed to NCI Program staff after the final summary statement is received.

16.2 Second-Stage Review for Comprehensiveness (Education and Training of Biomedical Researchers and Professionals and Community Service and Outreach, No more than 20 pages):

Many organizations that are dedicated exclusively to health care call themselves comprehensive cancer centers based on their self-assessment of their prevention, diagnostic, and treatment services. However, the term "comprehensive" as used by the NCI requires more than state-of-the-art care and services and includes a strong research base interactive with a wide spectrum of prevention, care, education, information and dissemination activities that broadly serve their local and regional communities and often the nation. These activities are supported by a broad array of Federal and non-Federal funding sources, such as research grants and contracts; prevention and control, training, and education grants; state awards; and private donations.

If peer review approves the *scientific* requirements for comprehensiveness, and the CCSG application is funded at any level, staff of the Center's Branch will contact the PI by letter to request a summary of the institution's programs in lay and professional outreach and education. Applicants will be given approximately six weeks to prepare and submit materials. The Parent Committee then determines whether to recognize the center as comprehensive based on the documentation provided. Since second stage reviews are typically scheduled only once per year, the interim between the first- and second - stage reviews may be as much as years, depending on the timing of the center's original application date.

Instructions for Application for Second-Stage Review of Comprehensiveness

- **Education and Training of Biomedical Researchers and Health Care Professionals:** The cancer center must sponsor or participate in education and training of biomedical researchers and health care professionals. Training of biomedical researchers includes appropriate programs for training MDs, and PhDs in laboratory, clinical and public health research (including cancer prevention and/or cancer control research). Cancer centers also should sponsor continuing education programs for practicing health care professionals (e.g., technicians, nurses, physicians) in the community or region served by the cancer center. These activities should cover a spectrum of topic areas, including early detection, diagnosis, treatment, and rehabilitation, and quality of life. Programs focused on cancer prevention and on encouraging community health care professionals to accrue patients to cancer clinical trials should also be provided. For this section of the application:

  -In Summary 2 format, provide a listing of training grants that support the award of degrees in nursing, behavioral sciences, and medicine, and that promote the specialized skills needed to practice in medical, surgical, radiation, and pediatric oncology, as well as rehabilitation, pain management, psychosocial services, and other relevant fields.

  -Describe briefly your training activities in these areas.

  -Indicate the total number of trainees and the number of under-represented minorities and special populations recruited to these programs.

  -Discuss your minority recruitment efforts in the narrative, including significant accomplishments and hurdles.

-List the continuing education programs conducted by your center for health care professionals and briefly summarize these efforts in a narrative description.

- **Community Service and Outreach:** A comprehensive cancer center must define the local community or region that it serves, and maintain productive service and outreach efforts to address issues of greatest concern to that community. When the service regions of comprehensive cancer centers overlap, centers must work with or complement each other. Programs or activities must address cancers of highest incidence, morbidity and mortality within the community and the region, and the needs of populations with disproportionate cancer incidence and mortality rates (e.g., minorities, Native Americans, people over age 65). Through leadership, technical assistance, advice, and other services, comprehensive cancer centers must facilitate NCI funded outreach programs (e.g., CIS) the programs of other local organizations (e.g., State Health Departments, State Cancer Plans, American Cancer Society Divisions), in their service area, as well as sponsor and encourage other local efforts through community organizations (e.g., hospices, support groups), hospitals and businesses. For this section of the application:

  -Define the center's local catchment area in terms of geography and population demographics, and discuss relevant cancer issues and problems.

  -Discuss how the center establishes priorities and uses its available expertise and resources to address cancer incidence and mortality among populations within the defined catchment area.

  -Provide a listing of service and outreach activities within the catchment area, including those that address the special cancer problems within the community.

  -Discuss your service and outreach efforts in the narrative, including those oriented to special populations, and provide any supporting documentation.

  -Discuss collaborative service and outreach efforts with for profit or not for profit programs, as well as with other centers, community hospitals, and private oncology practices in overlapping service areas and provide a listing of these collaborations.

  -Discuss how the center evaluates the impact of its service and outreach activities.

16.3 One-time Opportunity to Reapply for Comprehensiveness: A funded grantee that fails to receive the comprehensive designation at either the first or second stage of review may re-apply once during the grant project period. The re-application, which should address reviewer concerns, will be evaluated by the Parent Committee. Centers interested in re-application should contact NCI program staff for further information.

16.4 Retaining the Comprehensive Designation: If an NCI-designated Comprehensive Cancer Center's competing renewal application meets the scientific standards for comprehensive recognition from the Parent Committee but is voted an impact/priority score that does not merit funding, the center may retain the NCI comprehensive designation only for as long as the NCI maintains the "active" status of the CCSG through administrative actions.

Instructions for Submitting the CCSG Application

Where to Send the Application: Submit one original and **3 copies** of the CCSG application to the Center for Scientific Review (CSR), NIH, according to the instructions in the PHS Form 398 (rev. 06/09) kit. For a new or renewal, resubmission, or competitive revision application, enclose a cover letter naming the NCI staff person who agreed to accept the application for consideration.

At the same time the application is submitted to CSR, please send two complete copies to the NCI at the address below to facilitate scheduling and determination of whether additional information is needed for the review. The NCI address is:

Referral Officer
National Cancer Institute
6116 Executive Blvd, Room 8004, MSC 8329
Bethesda, Maryland 20892 – 8329 (for Express mail, use Rockville, MD 20852)
Tel: 301.496.3428
Fax: 301.402.0275

Acceptance of the Application: A Scientific Review Officer (SRO), located in NCI's Division of Extramural Activities oversees the peer-review process. Between submission and the completion of the peer review process, direct all communication to the SRO responsible for the CCSG review. The SRO supervises the review process to ensure a technically competent and unbiased review. While the application is in review, the SRO may consult NCI program staff on program policies and guidelines.

Upon receipt of an application, the SRO conducts a thorough review of the submitted materials with attention to the following elements:

- **Conformity with Guidelines:** Applications should exhibit the general organizational, administrative, and operational structure of cancer centers and request allowable and appropriate costs as per these guidelines.

- **Format:** Applications should be prepared in conformity with the PHS Form 398 (rev. 06/09) instructions to facilitate review of the submission. **Completeness of Required Information:** The applicant should ensure that all essential information is presented completely and unambiguously, to **facilitate the quality and consisten**cy of the review.

If an application is deficient in the elements above, depending upon the magnitude of the problem, the responsible NCI staff may:

- Defer the application to a later review cycle

- Return the application to the applicant without review

Modifications After Submission: Minor, unavoidable modifications of the application can be accepted up to 30 days prior to the site visit. Major modifications, however, may result in deferral by the SRO to the next round of receipt and review. Generally, new material should not represent major changes in the application as

written and/or presented. Whether to accept modifications of the application or additional information or to defer the application rests entirely with the SRO.

Reviews will be based on the material submitted at least **30** days prior to the site visit. Do not submit additional material after that time unless specifically requested.

Inquiries About the Application after Submission:

- **Before Completion of NCI Parent Committee Review:** Direct inquiries to the SRO, who is responsible for all aspects of the peer review process.
- **After completion of the NCI Parent Committee Review,** address questions to the responsible program director in the Office of Cancer Centers (OCC) or to the Director of the OCC or, for fiscal questions, the Grants Management Specialist.
- *Applicants may not contact any member of the site visit or the parent review committees about the review.*

III Peer Review of the Application

Types of Review

All CCSG applications undergo peer review under the authority and responsibility of the Scientific Review Officer (SRO). Site visit committees gather information for final evaluation by the Parent Committee (NCI Initial Review Group Subcommittee A or NCI IRG A). A full site visit encompasses a review of all application components. In some circumstances, a grantee may elect a limited site visit, which focuses only on the administrative, regulatory, clinical, and financial aspects of the application and center, including institutional commitment, administration, and clinical trials oversight (clinical trials office, protocol review and monitoring system, protocol specific research support, and data and safety monitoring).

Full site visit review is required for new applicants, for centers seeking an increase in funding of greater than 10% compared to the final year of their prior award or a change in designation, or for centers with a new director or other significant change. Full site visits may also be requested by any center director.

Limited site visits are only available to funded centers that have had no change in director since the last review, are requesting a budget increase of less than 10%, and have no other significant changes, including a request for a change in designation. Center directors should consult with NCI program staff before requesting a limited site visit to ensure that they understand the implications of this decision. Program staff will indicate eligibility for a limited site visit in the Prior Approval of Acceptance letter to the applicant.

The SRO contacts the center director well in advance of the site visit date to decide on the type (limited or full, see below) and appropriate length of time for the site visit, discuss the proposed agenda, and coordinate other site visit logistics.

Proper review of a complex center, whether at site visits or at the deliberations of the parent committee, requires evaluation by peers: scientists with substantial experience, a broad perspective on cancer research, and scientific, organizational, and administrative sophistication. Peers may be drawn from cancer centers or institutions without centers. Those who have not served on at least one center site visit in the last 3 years will undergo an orientation.

- **Full site visit reviews:**

  -A full review team will visit the center for presentations and discussion. The separate administrative review during the site visit will be as short as possible, based on the completeness of the application, to permit center administration to attend the site visit presentations.

  -Full site visits usually extend a maximum of 8 hours at the center, depending on the size and complexity of the application and center. Centers are encouraged to present formal scientific Programs in groups rather than individually to allow more time for discussion, and must present shared resources in a poster session format, so that reviewers can focus more of their time on the Center’s scientific Programs.

  -A written report of the site visit is provided to the applicant for factual corrections prior to the application’s final review by the parent committee.

- **Limited site visit reviews:**

  -Four to six weeks prior to the Parent Committee meeting, NCI staff, an administrative reviewer and several investigators with clinical trials expertise will visit the center to evaluate the administrative, regulatory, clinical, and financial aspects of the application and center, including institutional commitment, administration, and clinical trials oversight (clinical trials office, protocol review and monitoring system, protocol specific research support, and data and safety monitoring).

  -Four weeks prior to the Parent Committee meeting, regular and ad hoc parent committee members will submit questions generated from review of the paper application for clarification to the SRO; these will be forwarded to the applicant.

  -Two weeks prior to the Parent Committee Meeting, the cancer center will provide written responses to the submitted questions.

  -At the Parent Committee Meeting:

    - The center director and administrator may each give a presentation of no more than 10 minutes and respond to questions from the committee

    - Limited site visit team reviewers will present their findings.

    - The Parent Committee, supplemented by individuals with expertise appropriate to the scientific research described in the application, will discuss and evaluate each element of the application.

  -Because of the limited reviewer-applicant interactions, the submitted application must be complete.

Parent Committee Review: The Parent Committee is a chartered review committee of the NIH. After considering the written report of the site visitors, the viewpoints of NCI Parent Committee members who participated in the site visit, response of the applicant to the site visit report (in the case of a full site visit), and the deliberations of the full committee, it provides a final merit evaluation and a budget recommendation for the CCSG application in a Summary Statement, which is provided to the principal investigator as soon as available.

The Parent Committee also determines if the ***scientific*** (Stage I) criteria for comprehensiveness are met. If so the Center is invited by NCI Program Staff to submit additional material addressing the ***education, training, service, and outreach*** (Stage II) criteria for comprehensiveness. The Parent Committee determines comprehensiveness at a subsequent meeting after review of this additional material.

Ad hoc Review: Whenever conflicts of interest exist within the usual two-step peer review system of site visit and NCI Parent Committee, (e.g., an application submitted from the institution of a NCI Parent Committee Cancer Center Director), the SRO will conduct a single step ad hoc review in lieu of the usual two-step process.

National Cancer Advisory Board (NCAB): The NCAB is the final step in the peer-review process. The NCAB may concur with all peer-review recommendations, ask for re-review, or make some other recommendation. NCAB approval must precede funding.

Final funding decisions are made in accordance with the NCI's budgets for the Office of Cancer Centers during each fiscal year.

Process for Criterion Scoring: Prior to the site visit, assigned reviewers will submit to the SRO their criterion scores for the overall application on the five standard review criteria: Significance; Investigator(s); Innovation; Approach; and Environment, using the review criteria provided. These scores will be included in the Draft Site Visit Report and Summary Statement under the heading, Overall Impact/ Priority Score, but in keeping with NIH policy, will not be discussed as part of the review process.

As part of the evaluation and written critique on the Overall Impact/ Priority Score of the Center, reviewers will discuss and describe the extent to which the overall application meets the five standard review criteria, as delineated under the NIH enhanced peer review process. The evaluation of the five standard review criteria will be addressed for the application as a whole along with evaluating additional specific review criteria for CCSG applications. In the Overall Critique, under a subheading, Overall Impact/ Priority Score, the Chairperson will provide a summary that includes an evaluation of the Essential Characteristics and specific Overall Impact/ Priority Score review criteria that address these 5 criteria: Significance; Investigator(s); Innovation; Approach; and Environment.

In addition to the above review criteria, the criteria below will be applied to applications in the determination of scientific merit and the impact/priority score.

Criteria for Peer Review for Competing CCSG Applications

Overview: Cancer centers have a number of appropriate missions—research, education, and care. Nevertheless the CCSG predominantly supports the research mission of the center. The role of peer review is to assess the extent to which the center has promoted or is likely to promote excellence in research that may lead to a reduction in the incidence, morbidity, and mortality attributable to cancer to persons within their catchment area and beyond. Reviewers also evaluate how well the center's leadership, organization, and processes for development and evaluation facilitate scientific productivity, strengthen the institution's research capabilities, and enable its investigators to take advantage of scientific opportunities beyond what would have likely occurred at the institution without the CCSG.

Successful cancer centers:

Have a strong peer-reviewed research base in cancer-related science.

Add tangible value to the research base already in place within the institution.

Meet all six essential characteristics of an NCI-designated Cancer Center.

Reviewing Science in the CCSG: Science, not process, is the focus of the review. Even when process is to be specifically evaluated, such as with planning and evaluation or the ways in which flexible funds are utilized, the criteria for success are the scientific judgment behind, or consequences of, particular actions or decisions. In a CCSG review, assessment of scientific quality differs importantly from the familiar peer review of individual grants. It is not the role of peer review to re-examine individual projects that have already received fundable impact/priority scores. Rather scientific review of a CCSG should seek to address the major issues listed under Overall Impact/ Priority Score of the Cancer Center, page 66.

Assessing Merit Despite Institutional Diversity: The peer-review process will evaluate scientific merit and the value-added by the center across a great variety of institutions. Small institutions compete directly with large ones; centers organized only recently compete against distinguished cancer-research organizations which have existed for decades. In several instances, the center is comprised of a consortium of scientific institutions. NCI encourages peer review to recognize and reward scientific excellence, diversity and the variety of organizational forms. The flexibility inherent in these CCSG guidelines should result in the funding of centers with a variety of scientific agendas. The intentionally non-restrictive nature of CCSG requirements should allow constructing scientifically excellent centers around very diverse themes. ***Scientific excellence is not synonymous with large size,*** smaller institutions may develop a limited number of scientific Programs that capitalize on their specific scientific strengths or special populations. The primary consideration for reviewers is the merit of the Programs presented, not their number or size.

Some Restrictions on Allowable Budgets: Requested and/or awarded funds may not duplicate or replace costs normally included in the institution's indirect cost base or various services and benefits normally provided by the institution (e.g., purchasing services, personnel services, and other ancillary services) in support of other research organizations (other centers, departments, institutes, etc.). In general, CCSG funds should not be used to compensate for NIH/NCI administrative reductions of active research grants, cooperative agreements, and contracts. CCSG funds may not be used to pay for shortfalls in funded research projects due to over-expenditures on the funded project or NIH reductions in awards. The CCSG funds are not intended to supplement or offset any patient costs, even those directly related to clinical research protocols, including costs for parking, taxi fares, meals, or hotel rooms. The cost of clinical trials should be supported by their respective funded research projects. The CCSG, however, may support research pilot studies as allowed by the developmental funds and protocol specific research function, for institutional feasibility (pre-phase I) and phase I, PRMS-approved interventional clinical protocols. Signatures by the principal investigator and the business official on the face page of the CCSG application officially attest that all of the requested costs comply with these conditions.

To assure stringent and fair review across the diverse range of institutions applying for CCSG support, consider the following specific review criteria in evaluating the merit of the CCSG application and its key sections:

Essential Characteristics of the Center – Guidelines Section Parts I and II, 6.0 (merit descriptor for each)

Facilities

- Adequacy and appropriateness of the center's space & physical facilities in relation to its identity, objectives, activities.

Organizational Capability

- Effectiveness of the center's organization in taking full advantage of institutional capabilities in cancer research and in fostering scientific interactions and joint initiatives among programmatic elements.
- Adequacy and appropriateness of membership criteria; documented processes for evaluation of members, including non-aligned members, on a periodic basis, and compliance with these policies and procedures.
- Effectiveness of the center in use of external and internal cancer center advisory bodies (e.g., executive committee) for strategic planning, decision making, and priority setting.
- For consortium centers, adequacy of mechanisms in place to ensure that:

- Differences can be resolved among consortium institutions.
- Benefits of clinical research are uniformly available across consortium institutions to the population within the catchment area.
- Strategic goals of the center are being met through an integrated recruitment process.
- The center director has authority over all shared resources in CCSG-supported shared resources in collaborating institutions and to integrate scientists from all partner institutions into the scientific Programs of the center.
- All members have appropriate access to shared resources, participate in scientific Programs, and may assume leadership positions in the center, even if partner institutions are geographically dispersed.

Transdisciplinary Collaboration

- Level of effective transdisciplinary and translational collaborations among laboratory, clinical, and population science cancer center members and adequacy of mechanisms used by center to promote them.
- Extent to which collaborative activities within and among (inter- and intra-programmatic) Programs have added value to cancer related scientific activities.
- For consortium centers, adequacy of mechanisms in place to ensure that:

- Research is integrated across partner institutions as evidenced by programmatic structure and objectives, joint publications and grants and other transdisciplinary, cross institutional activities.
- The partnership is stable, as evidenced by a history of research integration (see above) and the provisions of formalized legal agreements.

Cancer Focus

- Breadth, depth, and significance of the cancer research base, as judged by the structure and objectives of the Programs, research support, and collaborative publications of center members

Institutional Commitment

- Extent to which the institution has met prior commitments and provided (or plans to provide) resources to insure that the center reaches its full potential.

- For matrix centers, evidence that cancer center status is at least equivalent to that of an academic department.

- Adequacy of:

-Space, positions and discretionary funds controlled by the center director.

-Cancer center access to clinical inpatient and outpatient facilities for the conduct of clinical trials.

-Oversight of faculty and staff critical to clinical research.

-The institution's plan to deal with a change in the directorship of the center.

- For consortium centers, adequacy of mechanisms in place to ensure that:

-The partnership is stable, as evidenced by a history of research integration (see above) and the provisions of formalized legal agreements.

-The center director has authority over all shared resources in CCSG-supported shared resources in collaborating institutions and to integrate scientists from all partner institutions into the scientific Programs of the center.

Center Director

- Appropriateness of the scientific and administrative qualifications and experience of the director in relation to the center's research activities and objectives.

- Appropriateness of the director's position within the institution (at least that of a department chair) and his/her representation on decision making committees relevant to center objectives.

- Appropriateness of the director's time commitment to the center's research activities.

- Adequacy of the director's formally codified authority over (and effectiveness in management of) the center's space and research resources, including:

-Appointment of new members and discontinuation of existing members

-Appointments of faculty necessary to enhance the research objectives of the center

-Inpatient and outpatient facilities necessary to achieve the center's clinical research objectives (in centers with clinical research activities)

-Philanthropy, clinical revenues, or other funding streams

- For consortium centers, adequacy of mechanisms in place to ensure that the center director has authority over all shared resources in CCSG-supported shared resources in collaborating institutions and to integrate scientists from all partner institutions into the scientific Programs of the center

Senior Leadership – Guidelines Section Part II, 7.1 (merit descriptor)

- Appropriateness of the qualifications and effectiveness of each senior leader in relation to his/her role in the research activities of the center.

- Appropriateness of the time commitment of each leader in relation to needs and objectives and to the difficulty and complexity of his/her responsibilities.

- Effectiveness of the team in working together as a group in addressing cancer center issues and planning strategies.

Planning and Evaluation – Guidelines Section Part II, 7.4 (merit descriptor)

- Effectiveness of external and internal advisory and evaluation activities on the development of the center's scientific activities.

- Appropriateness of the External Advisory Committee relative to the center's needs.

- Effectiveness in using the External Advisory Committee as a group, based on:

-Annual meetings of the committee as a whole.

-Production of a committee report with recommendations to the center director.

-Response to committee recommendations by center and institutional leadership.

Developmental Funds – Guidelines Section Part II, 7.5 (merit descriptor)

- Effectiveness in (or potential for) strengthening the centers identified strategic scientific needs, including use of funds in the prior project period, where applicable.

- Effectiveness in (or potential for) assessing scientific merit of research opportunities proposed by center members.

- Effectiveness of the center in use of internal and external advisory bodies to assist in identifying scientific opportunities and needs appropriate for the investment of developmental funds (development of new shared resources and areas of recruitment).

Center Administration – Guidelines Section Part II, 7.6 (merit descriptor)

- Appropriateness of the qualifications of administrative staff.
- Appropriateness of policies regarding use of cancer center space.
- Effectiveness of administration:

-In providing centralized administrative services important to the research activities of the center in center decision-making processes

-In oversight of shared resources.

-In budget, purchasing, and accounting processes.

-In support of faculty recruitment, payment, and review; membership application policies and process; arranging and documenting meetings organized by the center; and management of pilot projects review and awards.

-In representing the center within the institution, including the central grants office (e.g. level of support, assignment of applications and grants for center members, and overlap of functions), and clinical (e.g., in-patient, out-patient, and networks), and other pertinent entities.

- For consortium centers, adequacy of mechanisms to ensure smooth administration of CCSG functions across institutions.

Staff Investigators – Guidelines Section Part II, 7.3 (for each individual requested: approval as requested, or at a lower percent effort, or disapproval)

- For Research Staff Investigators:

-Service as Principal or Co-Investigator on at least one NCI approved peer-reviewed and funded research project

-Special, clearly definable role in helping the center achieve its scientific objectives (above and beyond own research support and those duties encompassed in another CCSG role, such as senior or program leader).

-Extent to which the investigator's proven record of scientific productivity and accomplishments, as well as current peer-reviewed support, justify the request for support.

- For Clinical Staff Investigators:

-Special, clearly definable role in helping the center achieve its clinical objectives (above and beyond own clinical research activities and those duties encompassed in another CCSG role, such as senior or program leader).

-Extent to which participation in the development and implementation of the center's clinical activities (e.g., authorship of clinical trials, accrual of patients on interventional trials, or leadership roles in cooperative

group studies) promotes the center's clinical and translational goals and therefore justifies the request for support.

Scientific Quality of Each Program – Guidelines Section Part II, 8.0 (merit descriptor for each Program)

- Overall scientific quality of the Program
- Extent of cancer focus.
- Extent to which the relevant scientific disciplines that enhance Program breadth and depth and maximize productivity are represented.
- Extent of value added by the Program in promoting transdisciplinary and translational research among its members and with members of other Programs.
- Judicious and justifiable selection of members of the Program, based upon evidence of participation.
- Effectiveness of Program leaders.
- Appropriateness of the percent effort requested for the Program leader in relation to the difficulty and complexities of his/her responsibilities.
- Extent of value added by the Program to the center.
- Interactivity of the Program as documented by agendas of Program meetings (minutes not required) and inter- and intra-programmatic publications. Of total publications, 10% inter- and 10% intra-programmatic publications constitute general benchmarks for a reasonably interactive Program. Publications should represent the broad diversity of Program members.
- For clinical and translational Programs, effectiveness in accrual of patients to all types of trials in relation to the patient population. This includes investigator initiated institutional trials; those that demonstrate leadership, interaction, and collaboration in other NCI-funded clinical programs, such as Cooperative Groups, SPOREs, and other multi-site clinical trial networks; and collaborative trials with industry. A total of 10% accrual to therapeutic and prevention trials constitutes a general benchmark for a reasonable level of protocol accrual.
- For consortium centers:

-All members participate in scientific Programs and may assume leadership positions in the center, even if partner institutions are geographically dispersed.

-Research is integrated across partner institutions as evidenced by programmatic structure and objectives, joint publications and grants, and other transdisciplinary, cross institutional activities.

Overall Quality of the Programs

- Overall scientific quality of the Programs.

- Value added by the Programs to the center.

Shared Resources and Services – Guidelines Section Part II, 9.0 (merit descriptor for each resource)

- Extent to which resource provides services to multiple investigators in the center.
- Extent to which the resource is strategically important to the science of the center.
- Quality of the science the resource supports.
- Quality of the product and cost-efficiency of the service (e.g., whether quality and costs compare favorably with equivalent services provided by an outside source).
- Appropriateness of the qualifications of staff.
- Appropriateness of the budget request in relation to the amount and quality of the service provided.
- For high throughput shared resources, breadth of use by, and benefit to, center members; for low throughput or specialized shared resources, benefit to members and accessibility based on a fair and equitable prioritization system.
- Where relevant, extent of compliance with NCI, national or international standards.
- If an institutional shared resource

-Adequacy of CCSG member access to the facility's services.

-Benefits center members receive as a result of CCSG support.

-Participation of the center in facility planning and oversight.

- For consortium centers, adequacy of mechanisms in place to ensure that all members have appropriate access to shared resources.

Protocol Review and Monitoring System (PRMS) – Guidelines Section Part II, 9.2 (approve, conditionally approve or disapprove)

- Appropriateness of the composition of the committee and the qualifications of its members, for ensuring sufficient size and breadth of expertise to conduct a critical, fair scientific review of all clinical research protocols involving cancer patients in the institution or institutions comprising the center.
- Authority and process for initiating, monitoring and terminating all cancer clinical research protocols in the institution or institutions comprising the center.
- Appropriateness of criteria and process for scientific review, taking into account the specific rationale, study design, duplication of studies already in progress elsewhere, adequacy of biostatistical input, and feasibility for completion within a reasonable time frame.

- Appropriateness of mechanisms for overseeing the prioritization of competing protocols from all sources (including cooperative group trials and industry trials) and thus, for ensuring optimal use of a center's clinical resources for scientific purposes.

- Adequacy of criteria and process for monitoring trials to ensure ongoing research is making sufficient scientific progress, including adequate patient accrual rates, and for terminating trials that do not meet scientific goals.

- For consortium centers, a single Protocol Review and Monitoring System governing all cancer clinical trial protocols across all the partner institutions.

Protocol Specific Research Support – Guidelines Section Part II, 9.3 (merit descriptor)

- Proposed studies comply with criteria for support, as outlined in Part II, Section 9.3

- Scientific quality and innovation of proposed studies

- Appropriateness of the number and percent effort of research nurses and data managers involved in the direct conduct of *institutional, investigator-initiated,* feasibility (pilot or pre-phase I) or phase I studies that are not funded via other peer reviewed mechanisms.

- Adequacy of the process for setting priorities in the assignment of these research nurses and/or data managers and for overseeing the progress of the research.

Data and Safety Monitoring Plan – Guidelines Section 12 (acceptable, unacceptable)

- General adequacy of the Plan itself in defining the general structure of the monitoring entity and mechanisms for reporting adverse events.

- For centers requesting funds for implementation of DSM functions (Note that budgets for DSM functions must be presented and justified separately from other components):

-General adequacy of DSM functions for the different kinds of studies (e.g., therapeutic trial, behavioral intervention, gene therapy trials that require evaluation, auditing, and monitoring) -NOT the specific evaluation of any particular study or the audit of that study.

-Adequacy of the expertise of individuals serving on key committees that perform DSM functions.

- For consortium centers, a single Data and Safety Monitoring Plan governing all cancer clinical trial protocols across partner institutions.

Minority and Gender Representation – Guidelines Section Part II, 10 (approval, disapproval)

- Appropriateness of the accrual of women and minorities to both therapeutic and non-therapeutic clinical trials in proportion to the center's catchment area based on demographic and accrual data provided

- When accrual is inadequate, adequacy of the center's plan to improve performance

Inclusion of Children in Clinical Trials-Guidelines Section Part II, 11 (acceptable or unacceptable)

- Appropriateness of the plan for including children in clinical trials or acceptability of the justification for exclusion of children in clinical trials

Overall Impact/ Priority Score of the Cancer Center (merit descriptor; overall) which includes the elements listed below:

Overall Impact

Reviewers will provide an overall impact/priority score to reflect their assessment of the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved, in consideration of the following five scored review criteria, and additional review criteria (as applicable for the project proposed).

Scored Review Criteria

Reviewers will consider each of the five review criteria below in the determination of scientific and technical merit, and give a separate score for each. An application does not need to be strong in all categories to be judged likely to have major scientific impact. For example, a project that by its nature is not innovative may be essential to advance a field.

Significance. Does the project address an important problem or a critical barrier to progress in the field? If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field? What is the overall quality of the cancer-relevant science in the center? What has the center contributed to the development of more effective prevention, diagnosis, and treatment for cancer (where appropriate)?

(Note: in the context of a P30 Cancer Center Support Grant review, the term 'project' refers to the Center application and 'project aims' refers to the Center's strategic goals.)

Investigator(s). Are the PD/PIs, collaborators, and other researchers well suited to the project? If Early Stage Investigators or New Investigators, or in the early stages of independent careers, do they have appropriate experience and training? If established, have they demonstrated an ongoing record of accomplishments that have advanced their field(s)? If the project is collaborative or multi-PD/PI, do the investigators have complementary and integrated expertise; are their leadership approach, governance and organizational structure appropriate for the project?

Innovation. Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions? Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense? Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?

Approach. Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Are potential problems, alternative strategies, and benchmarks for success presented? If the project is in the early stages of development, will the strategy establish feasibility and will

particularly risky aspects be managed? If the project involves clinical research, are the plans for 1) protection of human subjects from research risks, and 2) inclusion of minorities and members of both sexes/genders, as well as the inclusion of children, justified in terms of the scientific goals and research strategy proposed? Does the cancer center add value over and above the separately funded research efforts themselves? Have thoughtful, coherent scientific Programs been assembled and Program members selected to maximize the cancer-related interactive science in the parent institution as a whole? How do the different cancer-related scientific themes in the parent institution fit together in the center? What is the overall strength of the other components of the application?

Environment. Will the scientific environment in which the work will be done contribute to the probability of success? Are the institutional support, equipment and other physical resources available to the investigators adequate for the project proposed? Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements? What impact has the center itself had (or is likely to have) on the quality of the science, the productivity of the scientists, and the transdisciplinary activities of the institution relating to cancer? Have the choices for center membership made by its leaders resulted in a group of excellent cancer-focused scientists who are also committed to productive interactions with one another? What is the extent of value added by the CCSG to the Center?

Duration - Guidelines Section Part I, Budget and Funding Policies

- Recommended number of years of support

Overall Budget Recommendation:

If after evaluating all individual budget requests, the total budget seems excessive relative to the overall quality of the cancer focused science in the center, or in relationship to their NCI funding base, reviewers may recommend a single cut in the overall budget without identifying specific areas for reduction.

Criteria for Comprehensiveness – Guidelines Section Part II, 16 (approval/disapproval)

- **Stage I, Scientific Elements**

-Adequacy of the depth, and breadth in *each* of the three major areas of laboratory, clinical, and prevention, control and population sciences.

-Evidence of strong transdisciplinary research bridging these sciences.

-Note: Comprehensiveness for centers proposing consortia or affiliations may be based on research in the applicant institution or on supplemental strengths of all collaborating institutions.

- **Stage II, Education and Training of Biomedical Researchers and Health Care Professionals**

-Training of basic, clinical, and prevention and control cancer researchers as evidenced by a list of competitive training grants awarded to center investigators.

-Recruitment of under-represented minorities and special populations to research training programs as evidenced by data on total trainees and minority trainees and a narrative discussion of recruitment accomplishments and hurdles.

-Continuing education and training of health care professionals, in a spectrum of state-of-the-art cancer care and services, with a particular focus on prevention and on accrual of patients to cancer clinical trials, as evidenced by a list of training activities, seminars, and continuing education opportunities.

•Stage II, Community Service, Outreach and Dissemination

-The knowledge of the cancer problem in the community served by the center, as evidenced by demographic data, narrative discussion of special or underserved populations and pertinent cancer incidence and mortality data.

-Process for priority setting and use of available expertise and resources to serve the community in ways that will reduce cancer incidence and mortality.

-Outreach activities, including those that address the special problems of the community, as evidenced by a listing and discussion of such activities and any other supporting documentation

-Collaborations with not for profit or for profit outreach programs; and with other centers, community hospitals, and private oncology practices when service regions are overlapping, to develop complementary outreach efforts to maximally benefit the community, as evidenced by a listing and discussion of such collaborative efforts.

-Process for evaluation of the impact of outreach and dissemination activities on clinical and public health systems within the center's catchment area.

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